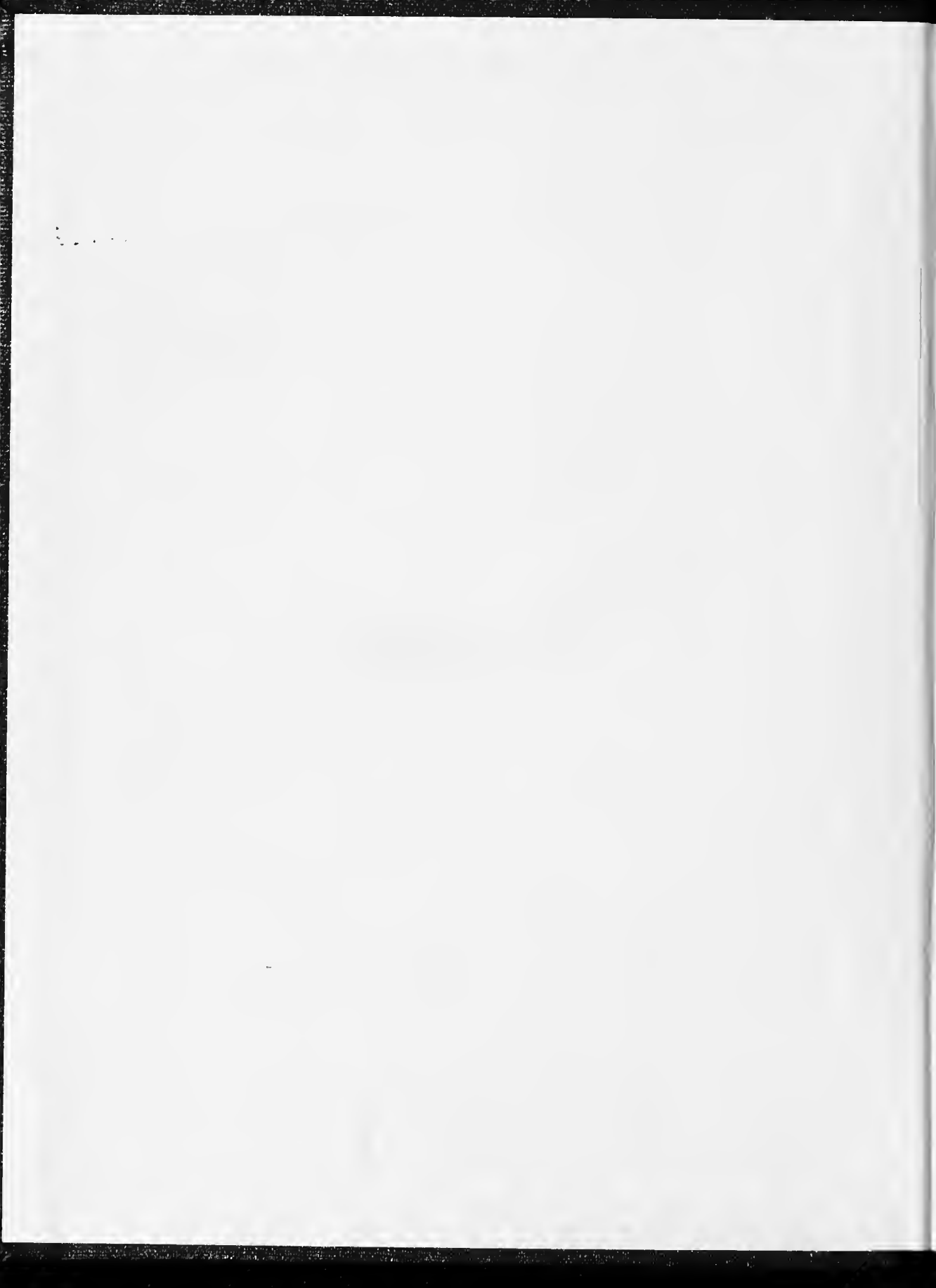


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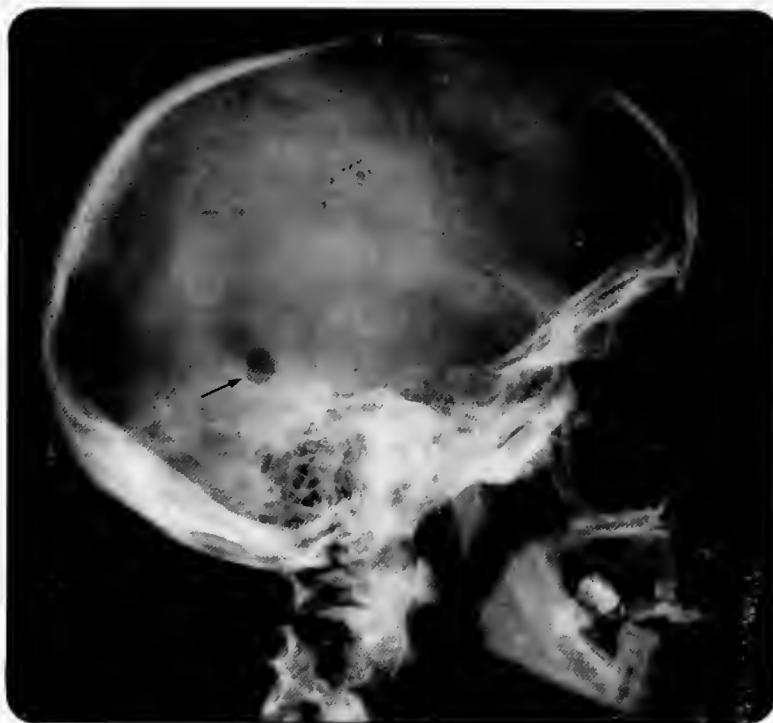
The Official Journal of the NORTH CAROLINA MEDICAL SOCIETY

January 1987, Volume 48, Number 1

Eosinophilic Granuloma: I Need This Like a Hole in the Head

David Darrow, D.D.S.
and Mark Linzer, M.D.

page 15



Indoor Radon

Dayne H. Brown, M.S. page 25

World Enough and Time: Hydrogen Sulfide Poisoning

Ronald B. Mack, M.D. page 33

The Boat People

Ernest Craige, M.D. page 36

Physicians as Science Writers

John M. Falletta, M.D. page 41

Table of Contents page 3

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volume 48, no. 1, January 1987

CONTENTS

Special Articles

- The Geography of Inpatient Admissions in North Carolina:
A Fifteen-Year Analysis *Thomas C. Ricketts* 5
Talking Sweet Reason: Some Optimistic Thoughts on the Future of Health Care *Alexander McMahon* 9

Learning Without Words

- Eosinophilic Granuloma: I Need This Like a Hole in the Head *David Darrow and Mark Linzer* 15

Scientific Articles

- The Pseudo-False Positive Meckel's Scan *Marcus E. Carr, Jr.* 18
Penetrating Head Trauma by a Boat Cleat *Frederick L. Potts III, F. Douglas Jones, and
Vegesena Prudhvi Raju* 21

Features for Patients

- Indoor Radon: A Residential Radiation Dilemma *Dayne H. Brown* 25
Dental Implants *Ronald D. Baker and David L. Koth* 28

Toxic Encounters

- World Enough and Time — Hydrogen Sulfide Poisoning *Ronald B. Mack* 33

Medical Education

- The Boat People: The 1986 Whitehead Lecture to the 1990 Class of the
University of North Carolina Medical School *Ernest Craige* 36

The Patient from Whom I Learned Most

- What I Learned from a Pregnant Teenage Diabetic Patient *Robert P. Schwartz* 39

Learning with Words

- Physicians as Science Writers *John M. Falletta* 41

Letters to the Editor

- 45

Bulletin Board

- New Members 49
Continuing Medical Education 50

- Classified Advertisements 55

- Index to Advertisers 56

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The Geography of Inpatient Admissions in North Carolina: A Fifteen-Year Analysis

Thomas C. Ricketts, M.P.H.

NORTH Carolina's hospitals differ from those in other states by their large number, wide distribution, and generally modest size. In 1984 there were 130 general, acute care hospitals located in 83 counties. Those hospitals ranged in size from 12 to 765 beds with 49 (38%) having fewer than 100 beds and only 16 (12%) having more than 400 beds. This system of hospitals reflects a dispersed, largely rural population organized around a tradition of independent county government.

Much has been written about whether the state needs this many hospitals given the growth of technology, good transportation, and a trend to lower hospitalization rates.¹ However, those discussions have focussed on the financial and organizational concerns of hospitals. The hospitalization patterns of the population have geographic dimensions as well; these are related to general market-area forces as well as the distribution of clinical resources and the relationships among physicians.

Patient Origins and Health Planning

Patterns of intercounty hospital admissions were first analyzed in 1972 by the Social Research Section of the University of North Carolina at Chapel Hill Division of Health Affairs. Figure 1 (next page) is adapted from that original analysis. The analysis was in support of a growing interest in the development of regional health planning areas. The passage of the National Health Planning and Resources Development Act of 1974 revived the interest in regionalization as the state prepared to develop a system of Health Service Areas centered around Health Systems Agencies. That process involved the description of rational hospital market or service areas. A discussion document was developed by the Health Services Research Center at the University of North Carolina at Chapel Hill which, again, described cross-county admissions.² Figure 2 (next page) is adapted from that analysis.

In 1985, there arose a different set of concerns over the future of the health care system. The continued viability of small, rural hospitals was in doubt and the fiscal stress on all hospitals was giving rise to concern over the distribution of charity care for indigents. Again, an analysis of the intercounty movement of inpatients was organized to determine if there were patterns of admissions that might serve to redistribute the burden of care among counties.

Similar maps to the ones prepared in 1972 and 1976 were developed using the same patient origin data with the addition of a special analysis of Medicaid patients, which became available for the first time in that year. Figures 3 and 4 (next page) are the results of that analysis.³

Each of the maps utilized hospital-reported patient origin data except for figure 4 which is based upon the Medicaid Claims File collected by the Division of Medical Assistance and organized for analysis by the state Center for Health Statistics. The choice of the 10%-or-greater level of cross-county inpatient movement was based on the comparability of that figure with the earlier analyses. Each figure will be discussed in the context of health and medical care system changes and conditions related to the data presented in the maps.

The Geographic Consequences of a Changing System

In 1969 there were 132 general, acute-care hospitals operating in the state distributed in much the same pattern as 15 years later. This earlier distribution of hospital resources met local needs very adequately and was the result of an eight-year period of consolidation which resulted in more beds in fewer hospitals. That trend was described to be the result of a growing "sophistication of equipment and personnel needed to provide good hospital care, and the cost of providing it." Such trends were said to "demand that hospitals be larger and fewer."⁴ The referrals to large, tertiary care hospitals outside the smaller counties was not very great, as figure 1 indicates, although the analysis of the distribution of hospitals and hospital beds from which the above quote was taken made much of the fact that the movement of patients across county lines indicated a strong need for regionalization of facilities; "such regionalization could form the basis for further planning for the future of the state's hospital system."⁵

The referral and admission patterns of five years later indicated the extent of this growing centralization of hospital services. Figure 2 shows a very large increase in the number of cross-county admissions and reflects the growing importance of the larger hospitals in a system that was focusing more and more on inpatient treatment using sophisticated technologies. The pattern of cross-county admissions in 1974 include several very distant referral paths that run against the rational division of the State into medical service areas. The teaching hospitals, especially those adjacent to medical schools, were drawing patients from counties close to large, non-teaching hospitals.

From the Health Services Research Center, University of North Carolina, Chapel Hill 27514.

Figure 1

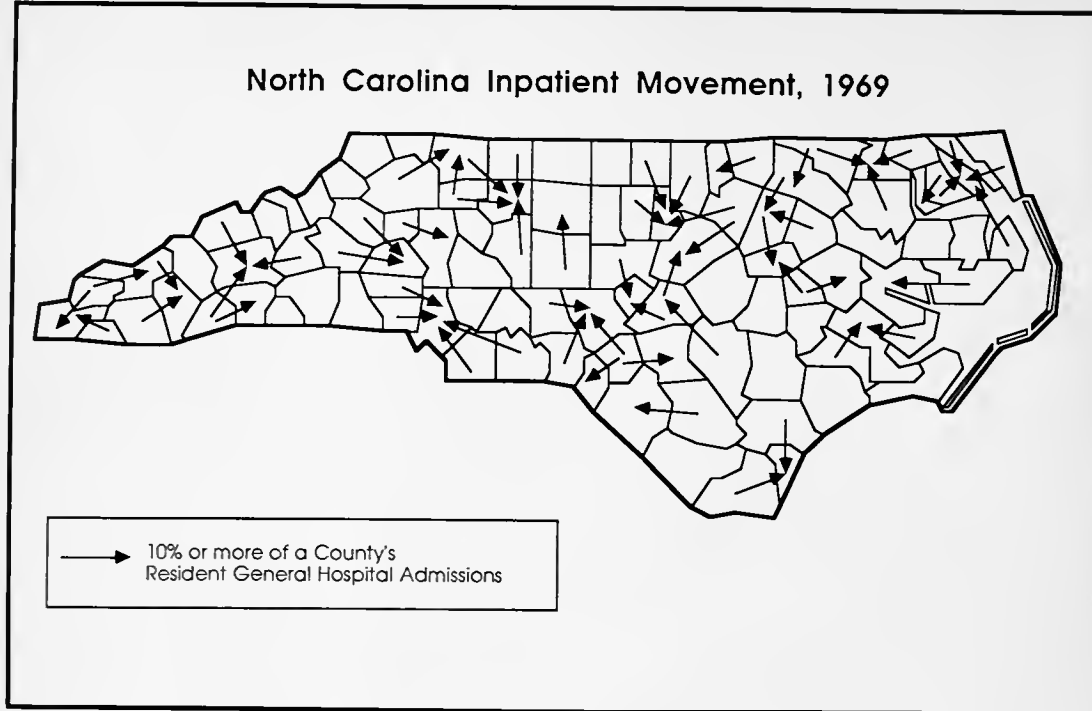


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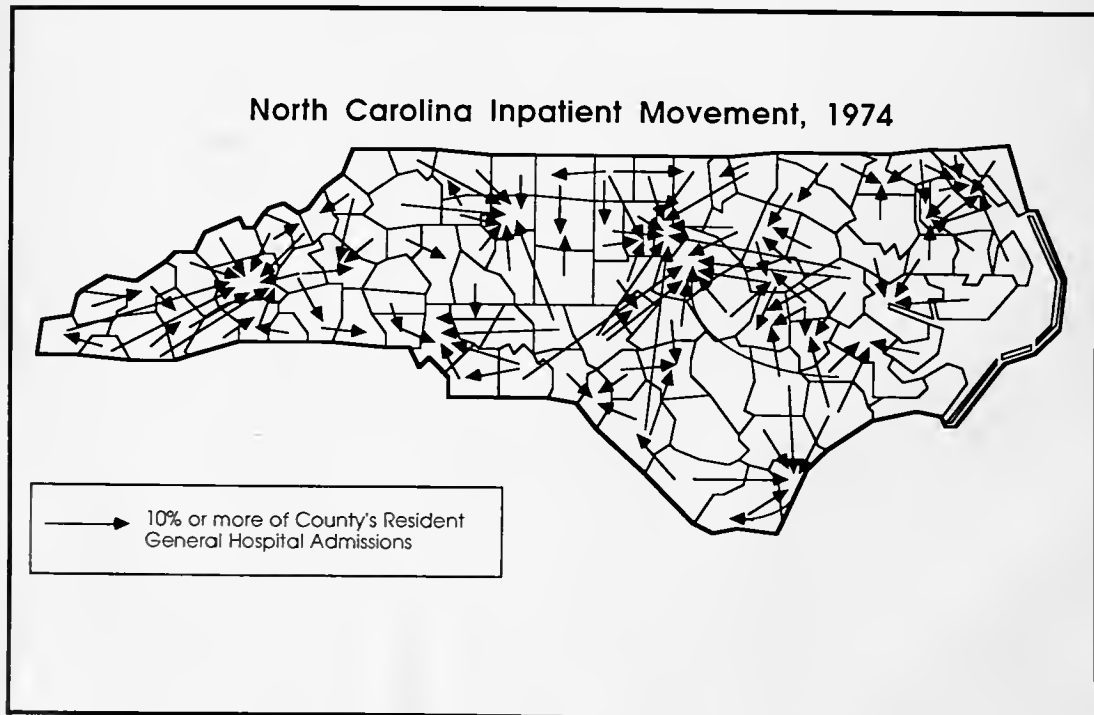


Figure 3

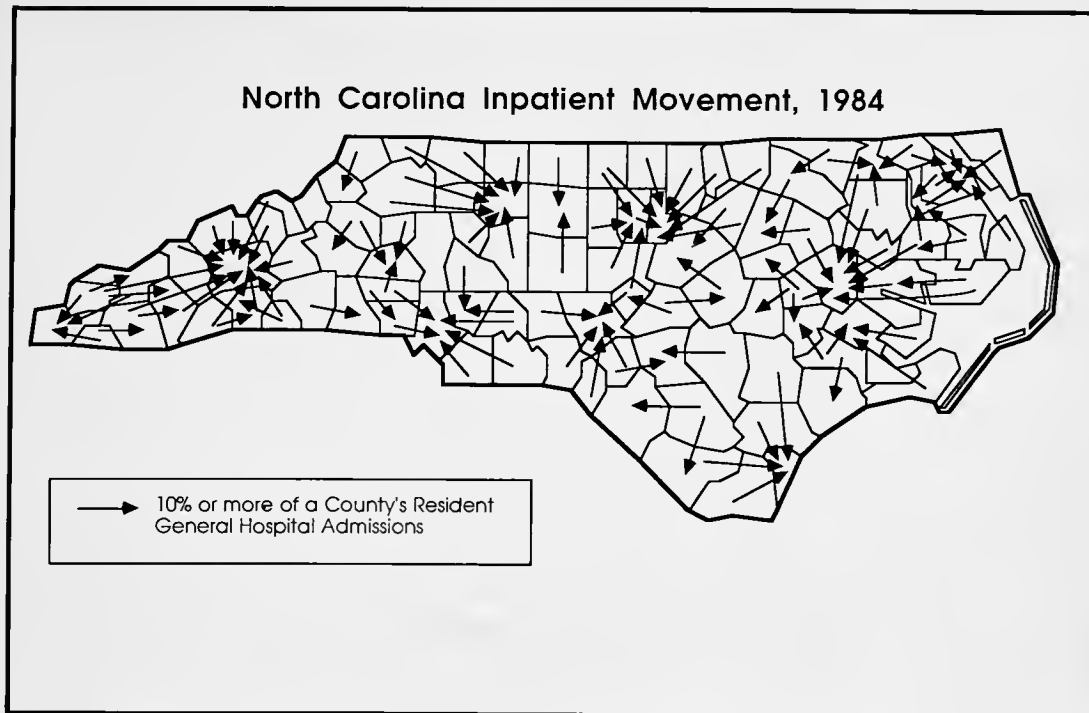
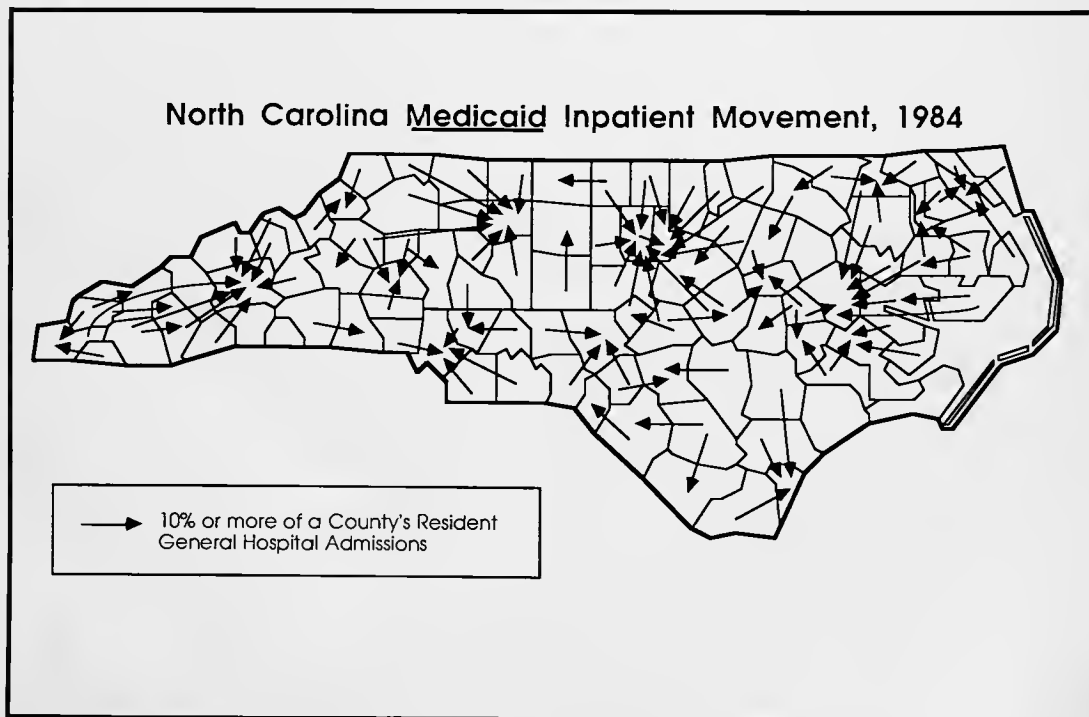


Figure 4



By 1984 the pattern of cross-county movement returned to a more "rational" distribution, although the volume of movement remained the same. The opening of the state's fourth medical school at East Carolina University, and the enlargement of the Pitt County General Hospital to include a wider range of clinical specialties and services, made Greenville the focus of a growing referral pattern. The central role of the hospitals in Wake County with regard to cross-county referrals appears to have diminished while a distinct service area appears to have been growing around Moore county. By 1980 there was an emerging concern that the pattern of referral and admission for Medicaid patients may have diverged from that of the general inpatient population which the first three figures depicted. The availability of patient origin data for Medicaid inpatients allowed for the same geographic analysis of that sub-population of inpatients for comparisons. Figure 4, which is based upon the same parameters as the other maps but restricted to patients for whom the Medicaid Program paid hospital bills, indicates that the pattern for Medicaid inpatients is much the same as for the general population, with few exceptions.

Analysis for the Future

The geographic analysis of patient movement is important in the description of service areas for planning and marketing purposes. However, in the absence of any cen-

tralized health planning apparatus, the decisions made in planning and marketing are made in, and applicable only to, the individual hospitals and hospital authorities; each will use this type of information to strengthen its individual market position. With the growth of outpatient-oriented medicine concentrated in health-maintenance and similar kinds of organizations, the next step is an analysis of the medical market areas in North Carolina with a focus on outpatient movement. Unfortunately, data for such an analysis are not yet available.

North Carolina does appear to have a market-based, regional hospital system clustered around seven or eight central places. That regionalization has only become evident in the past decade, after the enthusiasm for regionalization has died, unlikely to be revived in the near future.

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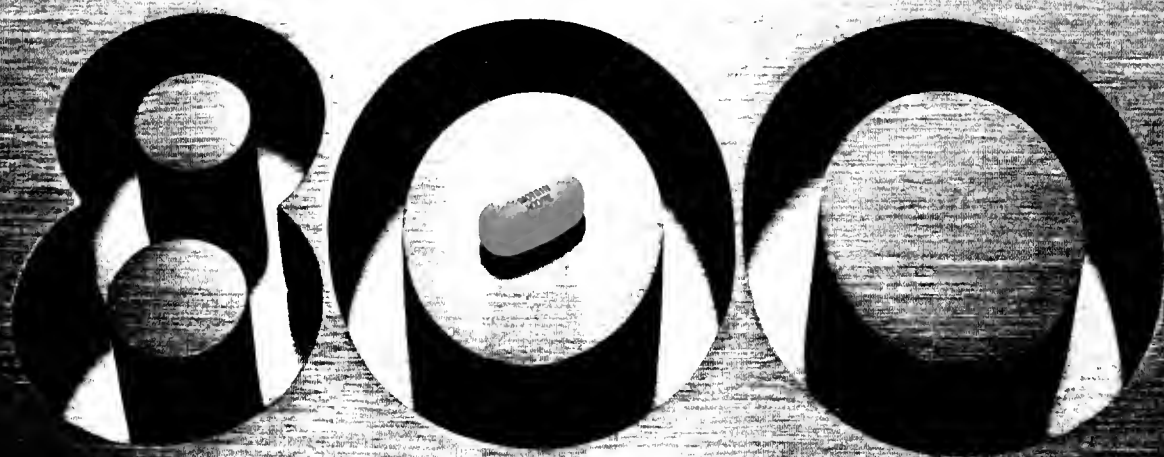
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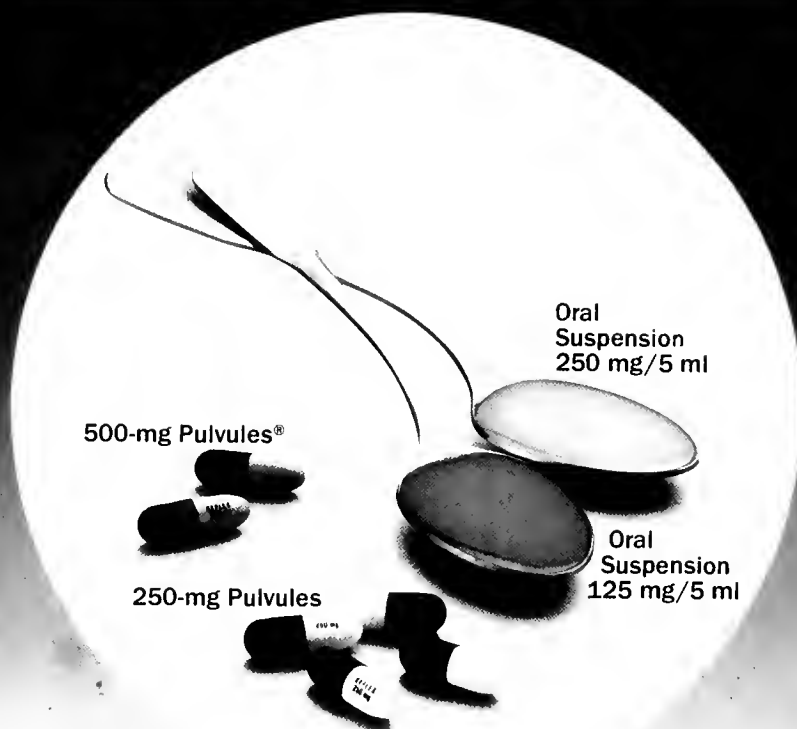
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Talking Sweet Reason: Some Optimistic Thoughts on the Future of Health Care

J. Alexander McMahon, J.D.

Present-day Hospitals

Everybody knows that inpatient hospital activity is down. I don't know whether it will go down further, but I know there is a great deal of variation in admitting practices throughout the country. If you look at the days of care per thousand people in southern Idaho, for example, it is vastly different from and lower than the rest of the country. We can't explain it. We see variation even within an institution. Some doctors just hospitalize differently from others.

If admissions are going down, it's not because payors won't cover needed care and quality is suffering. It's because some folks traditionally hospitalized don't need to be in the hospital. I am not going to guess where the admission trend will go in individual institutions. A lot depends on where you are and the institution. Duke Hospital hasn't lost in percentage of admissions as some of my friends in the rest of North Carolina have, for instance.

I think we ought to prepare in the future for a continued reduction in inpatient days, not completely offset by growth of population or of the elderly. I just see inpatient utilization continuing to drop, largely because of a drop in length of stay, but also because of an overall drop in admissions.

But if inpatient activity drops, it doesn't mean that health activity is dropping. At the American Hospital Association, we've got excellent inpatient hospital activity statistics. We don't have the same kind of trackage on outpatient activity, but I've a very strong sense that, while inpatient surgery is down, surgery as a whole is not. More surgery is being done on an outpatient basis.

That's not due to diagnosis related groupings. DRGs include absolutely no incentive for reducing admissions. As a matter of fact, there is every incentive for increasing admissions, yet that's not happening. Therefore, something more is going on than DRGs.

I think the increase in the number of physicians is the first influence. Changes in employment-related health insurance are number two, and DRGs are number three. Hospitals taught doctors about one-day surgery. Now, the doctors appear to realize, "Well, if I can do ambulatory surgery in the hospital, why can't I do it in my office?"

Many changes in the environment are bringing about very marked changes in the delivery of health services. They are giving different incentives to this system, particularly for patients to demand that care be given a little differently. So health services are still being delivered, and the total is still increasing, but those of us who traditionally have focused on the inpatient side need to think of services more broadly.

Another significant factor in the hospital area is the rapid increase in the number of elderly, particularly the old old, who are over 85. They consume substantial health care services, but not always necessarily on the inpatient side. You don't have to cogitate very long to understand the possibilities of an elderly couple, both past 85. One passes away. The other one may not need health services in a hurry in the traditional sense, but he or she may need some kind of homemaker or other support services.

If your hospital has a home health program, why not a health and homemaker program? Hospitals already have management skills and a lot of skilled people, including dietary and housekeeping. Yes, inpatient care is dropping, but there are many other opportunities to render services. I'm not talking about making money, although you've got to make money to survive and keep institutions open. But there are needs for services, and who better to fill those needs, to my way of thinking, than the hospitals? I don't think we're going to lose control of health care services if we meet community needs.

Health Care Systems of the Future

I suspect we're going to continue to see all kinds of differences in control lines, organizations, conglomerates and so on in health care systems of the future.

The investor-owned hospital segment is not growing. Investor-owned hospitals by ownership have been steady at 750 acute care hospitals for 15 years. What is growing is the investor-owned chain. Much of the growth of the chains has been from originally independent, doctor-owned hospitals. There has not been a great movement in not-for-profit or public hospitals turning investor-owned.

What is happening is multi-organizational development beyond hospitals. Some of it is blatant protectionism. If I tie up with others, they can help me and I can help them. Besides, we can sit around and talk and worry together. There is a rapid growth in multi-organizations. The interesting thing is there is more rapid growth in the not-for-

From Duke University Hospital, Department of Health Administration, Durham 27710. Based on a talk delivered in November 1985, when author was president of the AHA and chairman emeritus of the Board of Trustees of Duke University.

profit arena than there is in the investor-owned; for example, Sun Health, Voluntary Hospitals of America, American Healthcare Systems, Lutheran Hospitals and Homes Society of America in Fargo, North Dakota, etc.

With all the changes, we still have absolutely stable ownership of roughly 6,000 acute care hospitals — 3,300 not-for-profit, 1,700 publicly-owned, 750 investor-owned, and about 350 federal — Veterans Administration and military. With the ownership steady, the change that is going on is the development of these multi-organizations, alliances and so on. The health care system is becoming more interrelated, not only by ownership but by alliances of various kinds.

There are many similarities between not-for-profits and investor-owned. I see more differences within each of these segments than I do between them. I see some inappropriate entrepreneurial activities among some of my not-for-profit constituents, and I see some very community-oriented activities among some of my investor-owned constituents.

Look at the situation at Duke University. Duke is obviously not investor-owned. But the bond-holders from whom Duke borrowed \$100 million are looking at the Duke Medical Center to make very sure not only that interest and principal are being paid on time but that there is a sufficient margin to assure that they'll be paid next year and the year after that. They insisted on some triggers that, if Duke didn't make the required bottom line, would provide that security. Obviously, it's a different magnitude of bottom line than if Duke were investor-owned, but it needs a positive bottom line. The administration must run the place differently from the way it used to because it is getting money from the same kinds of capital markets that the investor-owned hospitals are. There are still some different kinds of requirements involved: stock-holders always have a bigger risk than bond-holders. But when not-for-profits moved away from Hill-Burton money and donations and went into the capital market, they needed to pay more attention to a record of revenues in excess of expenditures.

Ownership is not an all-important distinction. I see us all needing attention to revenue to assure appropriate access to capital markets, if we're to continue to grow. I think we are going to see some multi-institutional alliances using their broader asset base to provide capital market access. And because there are bright people throughout this system, they'll find other ways for independents, too, to assure access.

In examining the future health care system, I think that health care is bound to move more rapidly into capitation. Government, business, and even state agencies dealing with indigents are seeing and believing that a single price that covers the whole range of services — physicians, inpatient, outpatient, follow-up care, and so on — has better incentives than fee-for-service health care. They have been aided and abetted, of course, by the siren singers of capitation — Paul Elwood, Walter McClure, Clark Havighurst, in part, and Alain Enthoven — all of whom encourage appropriate incentives for the payor, the provider, and the patient.

An interesting thing about capitation is that this is one place where provider control can be recaptured. Kaiser-

Permanente, father of all HMOs, is provider-controlled: Permanente Medical Group on the physician side and Kaiser Hospital System on the hospital side. In the capitation area, you don't need a carrier. You will need some skills that hospitals don't traditionally have, such as marketing and actuarial and pricing skills, but you can acquire them in-house. I see great interest in capitation by business. If we're moving to capitation, hospitals will need additional skills. If we're moving to managed care by carriers, they must develop some skills that they have never shown before, including the ability to take some of those differences between practice patterns and straighten them out.

The Challenges of the Future

What are the things that will influence success in the future? Three things: federal government policy; local government action; and institutional practices.

National health policy is in an absolute shambles and I don't see it getting any better for at least the next four years. All congressional decisions are budget-driven and deficit-driven.

We've written a record in this country that is absolutely marvelous in dealing with crises. Look at the crisis that faced Social Security and brought about some remarkable changes in 1983. We don't deal with non-crisis situations nearly as well. We don't, unfortunately, have a real crisis in the health care world, either in Medicare or in Medicaid, so what we see instead is a political game.

The Congress of the United States doesn't want to admit that it over-promised elderly people in Medicare. Congress prefers to squeeze the doctors and the hospitals. Government knows that, with all the reduction in patient activity, the hospital field is in better financial shape than it's ever been. Even with the reduction in annual increases in expenses from 15 to five percent, many hospitals have the strongest bottom line ever. But that's the average. Many hospitals are in different shape. Again, it's the old story. You can drown in a river whose average depth is six inches.

I think we're going to see some additional government attempts to squeeze. Over the last couple of days, I've been figuring out how we can escalate the attention of key leaders to our problems and the future implications of these squeezes. Obviously, there's nothing secret about the best method. It means identifying hospital people with ties to congressional leaders.

The second area of challenge for the future is state and local government and the community. If the federal government is retiring from its large role in health care, we'll find more and more need for action at the state, county, city, and community level. Providing care for the indigent and the uninsured is the biggest single problem for health care and hospitals. When you look, you find that the uncompensated care hospitals give often goes to workers or dependents of employed people, who just don't have health insurance. Well, that may be a community-level problem. There certainly won't be a vast federal program. So we must do some better work in the local area. It means being involved with the business coalitions. It means being involved with political figures, making them more aware of what hospitals are doing.

The final area of challenge, and the key to success, is really the institution itself. I believe that here is where the real issues are to be resolved. I have a very strong feeling that because we're bright, we can solve some of these problems ourselves. It will, however, take a better internal environment than we've ever had before. I'm not sure that we've done the greatest job in all the world in explaining the roles and responsibilities of governance, management and medical staff. There is some thrashing around now to apply business principles to hospitals, and we have a good debate raging as to whether or not business ethics are applicable. I tend to think they are, but they must be applied a little differently. You have to remember what a complex institution a hospital is. It isn't like a typical business organized in a pyramid from the CEO on down. We're not even sure what role the medical staff plays: are the medical staff physicians the purchasers of hospital services? Whatever they are, they are very important, and I don't think hospital CEOs have done the best job of creating good relationships with the medical staff.

Let's look at the similarities between the hospital and the educational institution. Each has complex relationships among governance, administration, and staff. Universities have faculties, students, and alumni; hospitals have medical staffs, patients, and communities. From my observation, educational institutions are a little easier to govern and manage; I'm not sure why. Yet many educational institutions do not do any better in dealing with the faculty than hospitals do with the medical staff.

A good hospital-medical staff relationship will be extremely important for success in the future. It means getting a group of people who are uncertain about the future themselves — the doctors — and involving them in decision-making. Board members are restless, wondering, "Where is this institution of which I am a board member going?" Administrators wonder, "Will I have a job in a year?" And doctors ask, "Will I be able to treat my patients without interference?"

Successful hospitals maintain good internal relationships that are oriented to what they can do together to serve the community. Where that is the goal, the institution is not only surviving, it's thriving. With drops in occupancy of 20 and 25 percent, they're working together to provide non-inpatient services. They recognize that the locus of care may change, but patients haven't changed. People continue to need appropriate health care.

I look to the future with a great deal of confidence. We have the best health care system in the world. It was made good, made excellent, made the best by the dedication of physicians, by the dedication of administrative people, and by the dedication of all those board members whose efforts, attention, help, advice, and direction we've captured. And, yes, it's going to be different. I thank the good Lord. If it were going along smoothly, they wouldn't need you. So whatever happens, it is well that we are challenged, but we are up to the task, I assure you.

Questions

Q. In what ways might the Veterans Administration System change?

A. Let me broaden the question and say the government system, because I look at it in two different ways. We have had some discussions with the VA as to how they might use a civilian system whose occupancy is declining. The discussions are on hold right now because one other piece has to fall into place. The Administration says we need a means test for veterans over 65 the way we have for veterans under 65. What we have now in the VA system is a priority order. First, the veterans with service-connected disability treated for a service-connected problem. Second, service-connected disabled people with any kind of problem. I don't think government's dedication to the care of those people will wane. Third, indigent veterans. Below 65 there is a means test, but today anybody over 65 is considered to be indigent under the VA priority.

The two biggest DRGs in the VA now are schizophrenia and drug addiction-substance abuse. I heard the head of the VA say the other day, "We're becoming a system, in large part, of chronic disease hospitals." That's a different kind of care than lots of my constituents perceive when they talk about capturing some of these people.

The Department of Defense hospital system is vastly different. And there may be some real opportunities. A few weeks ago, Secretary Weinberger, followed by Bud Meyer, the Assistant Secretary of Defense for Health Affairs, stated that the military medical system needs to concentrate more on military medical readiness, not on providing a peacetime medical care system for dependents, retirees, and dependents of retirees.

Questions arise on how to keep the surgeons and the anesthesiologists and the nurses medically ready. We may have to find some ways to pull them into the civilian system. Then we have problems. They have problems. What are we going to do about the number of house staff they have? They don't know about that either. My guess is that they may have moved a little too fast.

But if the system is going to be down-sized, and the peacetime mission is put aside, then we are dealing with the kind of population that civilian hospitals are used to. More use of the civilian health care system would be a good way for the country, I think, to move. The Air Force particularly has an isolated base problem and care there may include some better use of reserves for military readiness. We are going to explore that use, and we will continue to explore the VA system.

Q. What is the magnitude of uncompensated care?

A. Estimates vary. If you're talking about all the uninsured, including some on Medicaid, you're talking about 35 million people. Out of 250 million total population, that's somewhere in the 15 percent range. It's not a large consumer group of health care services.

Nevertheless, we have to deal with uncompensated care for the indigent and those on the margin of poverty. It is our Achilles' heel in a competitive system when business and the federal government are trying to cut back their involvement in care costs for other than their own recipients. Obviously, demands for containing cost and taking care of indigent people at the same time put strains on the institution. But society will not allow people to go uncared for because of economic circumstances. As long as that

problem is there and festering, it can give rise to a resurgence of support for national health insurance.

You have to keep in mind that we have universal health insurance — for all intents and purposes — covering 85 percent of the people. If we work at the community level, we could get that figure to 90 or 95 percent. We have Medicare, we have group health insurance. We do have a declining Medicaid program, but at least we have access for most people. And you don't mess up a system that's working well for 85 percent for the other 15 percent. That is why, I think, national health insurance went by the board. I also think there is a recognition that the system today is changing in the right direction or at least changing in enough different directions that some of them must be right.

I see a great variation of change in the South and in the Midwest — HMOs, PPOs, different kinds of arrangements. I was in New York recently, and I was amazed that nothing much seems to be going on there. Why? Because that system has been so intensely regulated that the whole energy of the system is devoted to coping with regulations instead of delivering services to people. I think there is a recognition that, if we tried a universal single system, it would be an absolute mess. I see no interest any more; even the AFL/CIO has put it on the back burner. What may happen, however, and what we're seeing in South Carolina, Florida, California and elsewhere, in order to deal with the indigent care problem, is the states getting involved. So far, some of those systems seem to offer some hope of dealing with the problem.

Q. Will we reach a point where we have 15 or 20 systems providing all health care?

A. I doubt it. If we shrink to 15 or 20 systems, is Duke to be one of them? I don't see Duke wanting to lead one and I don't see Duke involved as part of one of the 20. I don't think the community-oriented trustees would be interested. I don't think that the medical profession, even in 20 or 30 years, will be ready to subject itself to that kind of discipline. What I see instead are these alliances that I mentioned — a loose confederation working together. I thought 13 years ago, when I went to Chicago, that we were about to embark on the new wave of alternative delivery systems that we're seeing today. It didn't happen. It wasn't until business became involved and interested in capitation, and the number of physicians increased sufficiently, and Medicare changed incentives, that we began to see change.

Health care is too localized a service delivery system. We don't have 15 or 20 bright enough people to run these 15 or 20 systems. We've got several thousands to deal with it on a more localized basis. I don't think those simple solutions are going to happen. It just isn't the American way of doing things.

Q. What is the future role of the American Hospital Association?

A. Three years ago, we went through an exercise to analyze whether or not AHA was positioned appropriately to provide services to a changing hospital constituency. We concluded we weren't. The House of Delegates was dominated by delegates selected by the state hospital associ-

ations, who generally came from the large 300-400 bed institutions in the not-for-profit sector. Some parts of the constituency were not being given adequate attention, and they felt they weren't being given adequate attention. So we created some seats in the House for multi-organizations, created some seats for the small or rural hospitals, created some seats for the metropolitan hospitals (the big public hospitals like Cook County and Bellevue in New York, and Charity in New Orleans, and the tertiary care hospitals). In addition, we've created some special sections, not for representational purposes but for service purposes. As hospitals get into home health, ambulatory care, long-term care — what can we do to help them?

The decision was made then to remain the American Hospital Association instead of the American Health Care Association. I think that was wise because, if we and you all do our jobs right, the hospital as it exists today will be the hub of the delivery system. Our job, then, is to help all of our constituents learn how to take advantage of that hub activity. As the locus of skilled people, hospitals can organize a continuum of care, including those services moved outside the hospital walls, such as health education and pre- and post-admission care. Some of the organizations don't think of themselves anymore as being even hospital-oriented. They are delivering care and looking to a future in which they will deliver more ambulatory care than inpatient care.

Writers in our magazines comment about how you deal with some of the new kinds of issues. How do you deal with marketing? How are you going to develop a new service? How are you going to price it? What kind of payment should you receive? How do you deal with the physicians? How can you develop a capitated system? How can you pay physicians without running into ethical pressures about rewarding them for not providing professional services?

We are trying to adjust to a competitive world where our constituents are no longer ready or able to sit down and work together. What they are doing is looking at one another, asking, "How can I beat the guy down the street?" or "How can I assure patient flow here to this institution or to this group of providers, including the medical staff?" But if we were to focus too much of our attention on that, then what would we do about the vastly greater numbers of hospitals that aren't to that point as yet?

It's very much a changing world and, I suspect, one of the things that is going to confront my successor head on. Top staff of AHA are meeting to revisit our mission at AHA. Who are our constituents? Are we continuing to serve them adequately? We've had a very constant membership of about 85 percent or higher of the hospitals. The ones we missed, for the most part, were small. But we kept that high membership because we have been changing as the constituency has been changing. We have to continue to do so.

Q. What about paying costs for those unable to pay?

A. I think it's going to have to come from all kinds of places. For the uninsured employed, we may have to figure out, with the carriers, a benefit package that will be lower in coverage and lower in cost and may be in that way

attractive, if not to the employer, to some of the employees. It may take some sharing through underwriting practices, a subsidy if you like. Some of it will continue to come from cost-shifting in the hospital, just getting enough from the paying patients to cover uncompensated care for the others.

Whether we're going to see more of the Florida and South Carolina "tax-the-provider" approaches, I don't know. It'll be interesting to watch how those work. Four or five years out, I think we'll see more state and community activity. That's where we must get our business friends involved to understand the community responsibility for taking care of the least advantaged members of society. So you can list ten sources and say all of the above.

Q. How will graduate medical education be affected?

A. We're going to see some reduction in Medicare graduate medical education payments. There are some candidates for reduction: elimination of funding for foreign medical graduates, for example. Of our 70,000 plus house staff in teaching hospitals today, probably 20,000 are foreign medical graduates. An ever-declining percentage of them are foreign-born. An increasing percentage of American foreign medical graduates are from "off-shore" medical schools, and some question the education they are getting.

Another method suggested in Congress for Medicare reduction is limiting the Medicare payment for a resident to the number of years for the first board eligibility or five years, which ever comes first. This method is designed to

eliminate subsidy for subspecialty training. What it shows is the depth of feeling in the Congress about the inappropriateness of using the Medicare Trust Fund to provide subspecialty training for people who are going to make a lot of money. They say, "Why provide government financed scholarships to people who are going to make \$200,000 a year? They ought to be able to take care of that on their own."

So there is a lot of thrashing around. The system isn't understood. This great, great system we have grows out of a lot of specialty training. It's my feeling the more we can keep government out, the better off we're going to be, because they are bound to make matters worse. What they will do is give us incentives to change things around so that we don't have the same process of training first in general medicine and then in specialties and subspecialties. So I don't know. The funding is vulnerable, because it represents a big amount of money to the government.

But let me tell you the good news. The good news is that regardless of what they do we're going to keep right on providing a first-rate education for physicians and specialty training too. If we have to find some other ways to do it, we'll do that too. I'm not sure that I can see how just yet, but I am confident we can.

My attention right now is focused on fighting major changes in what we're doing and I don't know how successful we'll be. But we're not going to see teaching hospitals fade away, and we're not going to see deterioration in graduate medical education. And we aren't going to see rapid increase in the primary care delivery people, because not all students are interested in that field. □

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Eosinophilic Granuloma: I Need This Like a Hole in the Head

David Darrow, D.D.S., and Mark Linzer, M.D.

- *Headaches do not usually warrant skull radiographs, but when the patient has a headache and point tenderness, a skull film may tell the whole story.*

HEADACHE is a common symptom; it is often the stimulus that brings a patient to the attention of a physician. Most headaches are attributable to muscle contraction, vascular disorders and conversion reactions. The diagnosis can usually be made by history alone. Radiologic and laboratory evaluation are indicated, however, when conservative therapy is ineffective or when signs and symptoms suggest an insidious or potentially serious pathological process. Recently, we were referred a patient with persistent headache and point tenderness over the painful area. Her x-rays revealed a surprising finding — a well-defined, solitary lytic lesion of the skull.

The "Hole" Story

The patient, a 37-year-old native of North Carolina, presented to her physician with a three-week history of left-sided headache. The headache was gradual in onset and was not associated with any precipitating or exacerbating factors. Initially the pain was dull and diffuse, but after several days the patient was able to localize a sharper pain superior to the left mastoid process. Over the three-week period, the pain increased in spite of self-medication with aspirin, and she sought the care of her doctor.

On examination, the skull was tender to palpation over the affected area. Possible mastoiditis was diagnosed, and the patient received prescriptions for ampicillin and an analgesic. Three days later, she returned to her physician with worsening pain. A skull radiograph showed the mastoid air cells to be unremarkable; however, a lytic lesion was noted in the left parietal area. The patient was sent to Duke Hospital for evaluation of the lesion.

At the time of her admission, our review of systems revealed no evidence of malignancy, brain abscess, meningitis, ear infection, trauma or congenital bony defects. Specifically, the patient denied any history of fever, chills, nausea, vomiting, trauma to the head, seizures, pain with mastication, ear pain or discharge, tinnitus, skeletal pain, abdominal pain, breast disease, or weight loss.

Physical examination was remarkable only for moderate

tenderness to touch in the area of the left mastoid process without a palpable mass. There was no lymphadenopathy to suggest infection or malignancy. A normal neurological examination indicated that involvement of the brain and meninges was unlikely. Laboratory data, including complete blood count with differential, electrolytes, urinalysis, electrocardiogram and chest roentgenogram, were all normal.

The Picture Tells the Story

With headache and point tenderness as our only remarkable features, we turned to the lateral skull film for further diagnostic information. The film revealed a solitary, well-defined "hole in the head" measuring eight millimeters in diameter and located in the intramedullary space of the posterior temporoparietal region (figure 1). This finding correlated with the site of point tenderness on clinical examination. The radiograph allowed us to narrow our primary differential diagnosis to a venous lake, an intramedullary dermoid tumor (a benign intracalvarial inclusion of epidermoid tissue), a dermoid cyst and eosinophilic granuloma. However, metastatic as well as primary intracranial malignancies were also diagnostic possibilities.

We then ordered a brain computed tomographic scan, which excluded any intracranial mass lesions. A radionuclide bone scan showed no evidence of other lytic lesions; the only area of increased activity was at the site of the skull lesion.

Making the Diagnosis Is the Treatment

The patient was taken to the operating room for biopsy of the lesion. The surgeon found a small bony defect filled with a pinkish-gray soft tissue. Pathologic examination of the tissue revealed large collections of plump histiocytes with normal round nuclei interspersed focally with collections of eosinophils — findings diagnostic of eosinophilic granuloma. The surgical site was then curetted, irrigated, and patched. The patient was discharged in good condition on the first postoperative day. One year after surgery, the patient continues to do well. She has had no further pain and has developed no new bony lesions suggestive of recurrent eosinophilic granuloma.

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Figure 1. The lateral skull film, with the arrow indicating the location of the "hole in the head" superior to the mastoid process.

While the differential diagnosis of osteolytic lesions of the skull is extensive (table 1), numerous entities can usually be eliminated simply on the basis of history, physical examination, and radiographic appearance of the lesion on plain films.¹ Lesions of eosinophilic granuloma will exhibit well-defined borders with a beveled appearance, correlating with the different levels of bony destruction. Patients with defects, cysts, hematomas, and infections of the calvarium usually give a history of head trauma or prior surgery. Distortion of the skull and a characteristic "ground glass" radiographic appearance with accompanying sclerosis suggest the diagnosis of fibrous dysplasia. Paget's disease is suspected when the history includes a change in hat size, and it is often confirmed by laboratory studies. In metastatic disease and multiple myeloma, there are usually multiple lesions with more poorly-defined margins. Meningoceles and encephaloceles are characterized by a midline occipital defect, while normal anatomical variants (including emissary channels, Pacchionian granulations, and parietal foramina) usually occupy a parasagittal position in the parietal region. A cavernous hemangioma has a typical "soap bubble" appearance due to bony spiculation. Rarely, a slow-growing glioma or other brain tumor may cause a single bony erosion, but these are usually accompanied by neurological changes and calcification within the lesion. Biopsy was necessary to distin-

guish between these diagnostic entities. Furthermore, if eosinophilic granuloma were the correct diagnosis, excisional biopsy with curettage is usually curative.

A Disease of Histiocytes

Once included in the spectrum of diseases known as histiocytosis X, eosinophilic granuloma (EG) now more appropriately denotes a benign solitary disease of bone.

Table 1
Differential Diagnosis of Solitary Lytic Lesions of the Skull

Eosinophilic granuloma
Multiple myeloma
Metastatic disease (e.g., breast carcinoma)
Bony defects, cysts (e.g., dermoids), hematomas
Osteomyelitis
Fibrous dysplasia
Paget's disease
Meningocele/encephalocele
Emissary channels, Pacchionian granulations, parietal foramina
Brain/meningeal tumors (rare)
Arteriovenous malformations (rare)
Cavernous hemangioma
Venous lake
Intramedullary epidermoid tumor

The Hand-Schuller-Christian eponym is presently reserved for multifocal cases of EG. Patients with this disease may present with all or part of the classic triad of exophthalmos, diabetes insipidus, and bone destruction. The Letterer-Siwe syndrome, another of the histiocytoses, is a disease of infants characterized by lymphadenopathy, hepatosplenomegaly, bleeding diatheses, bone and skin lesions, and an exceedingly high mortality rate. The common pathologic lesion in all of these diseases is the proliferation and infiltration of tissue by histiocytes which fuse into Langerhans giant cells. These cells are believed to cause a local eosinophilia by releasing chemotactic factors that attract eosinophils.²

EG is a disease of children and young adults with a slight predilection for males. It usually presents as a solitary osteolytic lesion of a long or flat bone (most commonly the skull and femur in children and a rib in adults) with pain and tenderness around the affected site. The skull is the most frequently involved area in unifocal EG,³ and therefore it is not unusual for patients to describe these local symptoms as headache. Since 90% of patients with unifocal skull lesions of EG will also present with a palpable mass,³ physicians caring for such patients will suspect that the headache is an unusual one and will pursue further diagnostic studies. Our patient did not have a palpable mass, but the unilateral nature of the headache in association with point tenderness alerted her physician to the fact that this was not a "routine" headache.

Patients with EG will usually have normal laboratory studies. Occasionally, there will be an elevation in the eosinophil count, erythrocyte sedimentation rate or immunoglobulin level. Diagnosis is usually suggested by plain film radiography as in our patient. Computed tomographic scanning aids in revealing the extent of individual lesions and the presence of associated soft tissue lesions. Bone scan will confirm that the lesion is unifocal and establish a baseline for follow-up studies. Definitive diagnosis, however, is made by excisional biopsy. The description of the pathology in our patient is typical of the disease.

Initial treatment of all lesions of EG is by curettage at the time of biopsy. Low dose irradiation of weight-bearing bones is usually suggested, but there is no evidence that irradiation of skull lesions improves the extraordinarily low recurrence rate obtained by surgery alone.³ Recurrences, when they do occur, are most common in patients first presenting as infants or young children, and have been detected as much as twelve years after initial presentation.³ It is usually recommended, therefore, that skeletal survey by bone scan and/or plain film be performed every six months for at least two to three years, both for detection of new lesions and for follow-up of the previously affected site.

William Heberden, in his *Commentaries on the History and Cure of Diseases*, remarked: "The nature of headaches is extremely obscure. Their manifest causes are very various and often contrary to one another. They probably therefore arise from different disorders. . . ."⁴

Persistent headache symptoms always demand close scrutiny. Although skull x-rays are rarely indicated in the pursuit of obscure headache, a palpable mass or point tenderness does indicate a need for skull films. The physician should not be too surprised if such films disclose a "hole in the head." In the case of eosinophilic granuloma, both headache and disease may be cured by making the diagnosis.

Acknowledgment

The authors wish to express their appreciation to Dr. James Vogler for his review of the radiographs in this case.

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The Pseudo-False Positive Meckel's Scan

Marcus E. Carr, Jr., M.D., Ph.D.

- *A cautionary tale about interpreting Meckel's scans, the procedure of choice for confirming the diagnosis of Meckel's diverticulum.*

THE sudden onset of massive gastrointestinal bleeding in an otherwise healthy child or young adult should raise the possibility of bleeding from an ulcerated Meckel's diverticulum. Arising from an unobliterated yolk sac, this defect is the most common congenital abnormality of the GI tract. Due to its usual location, within 100 cm of the terminal ileum, this anomaly does not lend itself to fiberoptic detection. Likewise, standard barium contrast studies including upper GI, small bowel follow through, and barium enema are usually unrevealing. While enteroclysis — the direct injection of contrast material into the bowel — may be useful, the relatively simple and rapid 99mTc pertechnetate Meckel's scan, developed in the late 1960s, has become the procedure of choice for confirming this diagnosis.^{1,2}

Both false-positive³ and false-negative⁴ results have been reported with this technique. The case reported here is of a healthy graduate student whose diagnosis was missed despite several Meckel's scans which, while positive, were only faintly so and were erroneously called "false-positive." The delay in diagnosis resulted in a second episode of life-threatening hemorrhage.

Case Report

The patient, 23 years old, first developed diffuse abdominal tenderness, post-prandial diarrhea, and bloating at age of 20. After two weeks of symptoms, she passed a large, dark red, bloody stool. In the emergency department, she was orthostatic (pulse rise from 90 to 140 upon standing) and anemic (hematocrit 29%, hemoglobin 10 mg/ml). She denied a history of melena, gastritis, peptic ulcer disease or inflammatory bowel disease. Physical exam revealed only minimal tenderness of the left lower quadrant. Stool was guaiac positive; coagulation screens were normal. Upper endoscopy failed to reveal peptic ulcer disease or gastritis, sigmoidoscopy was negative for hemorrhoids, and barium contrast studies of the stomach and upper small bowel were negative for mass lesions or inflammatory bowel disease. Polyps and inflammatory bowel disease were not found on air contrast barium enema. Her

stools gradually became guaiac negative and her hematocrit remained stable at 29 without transfusion.

In a final effort to identify a bleeding site, a 99mTc pertechnetate Meckel's scan and a sulphur colloid scan were performed on the day of discharge. The one- through ten-minute films of the pertechnetate study revealed an area of increased tracer uptake in the right lower quadrant. Since the area appeared before and did not persist as long as the stomach activity, it was felt unlikely to be a Meckel's diverticulum. The sulphur colloid study was faintly positive, indicating possible bleeding, in the same area. Besides a Meckel's diverticulum, differential possibilities included leiomyoma of the uterus or bowel, or intrauterine pregnancy. A pelvic ultrasound demonstrated a normal uterus without evidence of pregnancy. A repeat Meckel's scan one week later again showed an area of increased uptake in the lower abdomen just superior to the bladder. Since the area of uptake corresponded to the position of the uterus on ultrasound, and the patient had recently completed her menstrual period, this was felt to represent normal physiologic uterine uptake, "Uterine Blush."⁵

The patient did well for three years but then had the onset of abdominal pain in the left upper quadrant. After three weeks of symptoms, she awoke feeling well only to note blood in her stool after painless defecation.

Evaluation in the emergency room revealed: blood pressure 150/100 mmHg, pulse 90 beats/min, and hematocrit 37%. There was no orthostasis. Sigmoidoscopy to 20 cm revealed guaiac positive stool above that point. While in the emergency room, the patient suddenly felt faint and became sweaty and pale. Supine blood pressure fell to 90/60 mmHg; she began to pass large quantities of maroon colored stool. Repeat hematocrit prior to hydration was 32%. Her blood pressure fell further to 70/60 mmHg requiring rapid fluid replacement (4L crystalloid given intravenously over 30 minutes).

Nasogastric aspirate was guaiac negative. Emergent sulphur colloid scan failed to reveal the source of bleeding. After transfusion of three units of packed red cells and two units of fresh frozen plasma her hematocrit stabilized at 36%. Colonoscopy, including visualization of the distal 10 cm of the terminal ileum, revealed normal bowel. Biopsies of the terminal ileum were normal. A Meckel's scan showed an area of increased uptake in the mid-abdomen below the umbilicus (figure 1). The image persisted for thirty minutes and was felt consistent with a Meckel's

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Figure 1. A fifteen minute image of a ^{99m}Tc pertechnetate Meckel's scan. An area of tracer uptake by ectopic gastric mucosa is seen in the mid-abdomen as indicated by the arrow.

diverticulum of the small bowel. At laparotomy the diverticulum, found adherent to the underside of the umbilicus, was excised. Pathologic evaluation revealed gastric epithelium and Brunner's glands within the diverticulum and a focal area of ulceration.

Comment

Meckel's diverticulum results from failure of the omphalomesenteric duct to obliterate and occurs with an incidence of 1-2%. It was initially thought to cause a 25% complication rate, but Soltero, et al. found this not to be the case. They demonstrated only a 4% incidence of complication in children and young adults.⁶ The rate decreased linearly with age and was virtually zero after 70 years of age. The most common complications are obstruction (31%), bleeding (25%), inflammation (24%), and perforation (12%). Yamaguchi et al. found bleeding to account for 11.8% of complications attributed to Meckel's diverticulum in a series of 600 patients.⁷ Bleeding complications are much more common in children less than ten years of age, and represent the most common complication in this age group;⁶ hemorrhage in patients over the age of thirty is extremely rare. Fifty-seven percent of symptomatic Meckel's diverticuli contain gastric mucosa,³ the presence of which increases the incidence of bleeding.⁷

After pertechnetate was introduced for brain scanning in 1964, the tracer was noted to be selectively concentrated and excreted by the mucoid surface cells of the gastric mucosa. Since pertechnetate is concentrated in gastric mucosa, and since ectopic gastric mucosa is known to occur in symptomatic Meckel's diverticuli (particularly those that bleed), Harden et al. suggested the use of pertechnetate

as a noninvasive technique for diagnosing Meckel's diverticulum.¹ In 1981, Sfakianakis, reviewing the ten-year published experience, found the sensitivity to be 85% and the specificity to be 95%.³ False-positives (2%) may be caused by the presence of ectopic gastric mucosa in gastronomic cysts, enteric duplications, and duplication cysts. False-negative scans, the reported incidence varying from 2% to 50%, may result from necrosis of the Meckel's tissue, or from dilution of the dye by bleeding.⁴ Modifications of the original technique have included stimulation of gastric mucosa uptake of technetium by pentagastrin, and increased mucosa retention of technetium by cimetidine.

Another potential cause of false-positive Meckel's scans, the uterine blush, was first reported by Burt et al. in 1981 when they noted uterine activity after injection of pertechnetate.⁵ In a subsequent study, 73% of women with regular menses demonstrated a uterine blush during the menstrual or secretory but not the proliferative phase of the cycle. Burt et al. recommended ultrasound examination of appropriate patients to exclude uterine blush as the cause of low midline abdominal uptake.

Given the foregoing information, the initial management of this patient would appear to have been entirely appropriate. Nevertheless, she was discharged without a diagnosis and suffered a subsequent life-threatening episode of hemorrhage. The first Meckel's scan revealed a vascular area in the right lower quadrant, which also appeared very faintly on a sulphur colloid flow study. Since the ectopic activity did not persist as long as the gastric activity, this was felt not to represent a Meckel's diverticulum. Differential possibilities included leiomyoma of the uterus or bowel, or placental activity secondary to intrauterine pregnancy. An abdominal ultrasound failed to yield evidence of either of these possibilities. A second Meckel's scan performed during the patient's menstrual cycle once again revealed an area of increased uptake, this time in the area of the mid-pelvis. Comparison with the previous ultrasound study resulted in the conclusion that this represented a false-positive scan caused by uterine blush. These two scans actually represented either true positive or else false-positive/false-negative scans. In the latter case, falsely positive in the area of the uterus and falsely negative in the area of the diverticulum.

Given the lack of a diagnosis in this patient, one approach would be to repeat the Meckel's scan during the proliferative phase of her menstrual cycle (thus decreasing the likelihood of a uterine blush) while stimulating gastric uptake by pentagastrin and/or stimulating gastric tracer retention with cimetidine. Proceeding to enteroclysis would be a second option.

This case re-emphasizes several basic but often forgotten rules of medicine. First, patients do not bleed without a reason. If we accept the Meckel's scan as being falsely positive due to uterine activity, why did the patient bleed? Second, discharge without diagnosis may be more than intellectually unpleasant, it may be dangerous. Third, overreliance on technology may be a trap. One must be willing to question test results when they are at odds with one's clinical assessment. This is particularly true when, as in the present case, a test is "positive" but interpreted as

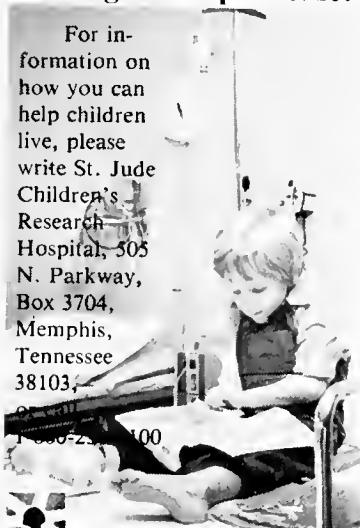
being negative — that is, a “false” positive. Fourthly, persistence has its virtues. In 1933, Charles Mayo wrote: “Meckel’s diverticulum is frequently suspected, often looked for, and seldom found.” The key to the evaluation may well be the persistence of the clinician and the extent to which he or she pursues the diagnosis. As suggested by Wilton et al., if you think the patient has a Meckel’s diverticulum and the initial scan is negative, repeat the scan.⁴ And if the test is “positive” in the right setting, it is likely that this is a “true,” not a “false,” positive; or, as eloquently stated by the late radiologist and educator Dr. George Himadi: “I’ll see it when I believe it.”

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Penetrating Head Trauma by a Boat Cleat

Frederick L. Potts III, M.A., M.D., F. Douglas Jones, M.D., and Vegesena Prudhvi Raju, M.D.

- *This case report of low velocity penetrating skull injury is interesting because of the mechanism of injury, the nature of the object, the dramatic radiologic appearance, and the absence of both loss of consciousness and neurologic sequelae.*

LOW velocity, penetrating head trauma has been caused by every conceivable object including nail, needle, icepick, pencil, scissors, rearview mirror, car antenna, fan blade, and other bizarre objects, with the most common being a knife blade.¹⁻⁷ Our patient, a four-and-a-half-year-old child, suffered impalement of his head by a boat cleat.

The boy was standing on the deck of a family-owned pleasure boat when another, larger boat sped by causing a large wake, such that he lost his balance and fell head-first onto a mounted boat cleat. The cleat impaled into the child's left forehead and, as his momentum caused him to flip over the side of the boat into the water, the screws anchoring the cleat were stripped from the fiberglass boat. The child was quickly retrieved from the water, crying and fully conscious.

With the boat cleat impaled, the child was rushed to a local emergency room where he was found to be neurologically intact. Pediatric Diphtheria-Tetanus toxoid and a prophylactic antibiotic were given, and a standard paper cup was placed over the exposed part of the boat cleat to protect the area from additional trauma.

The child was then transported, with cervical spine immobilization, via helicopter to the regional trauma center in Greenville, North Carolina, where, on arrival, the physical exam revealed a frightened but neurologically intact patient, with a metal boat cleat impaled in the left frontal skull just behind the hairline approximately 2-3 cm left of midline (figure 1). Vital signs were stable and cervical radiographs were normal. Trauma Score was 16.* Skull radiographs revealed an impaled, metallic foreign body approximately 5 cm into the left frontal cortex, with a depressed skull fracture (figure 2, next page).

The patient was taken to the operating room where the cleat was removed intact, and a left frontal craniectomy



Figure 1. Boat cleat impalement of skull.

with débridement was performed under general endotracheal anesthesia. The depressed skull fracture was repaired and the patient started on phenobarbital prophylactically.

Postoperative computed tomography of the head revealed contusion at the site of injury without evidence of retained bone fragments. The patient was treated with intravenous antibiotics for a total of seven days. The postoperative course was unremarkable and the patient was discharged home on day ten on phenobarbital. A one-month follow-up revealed no complications.

Discussion

When initially seen in the emergency department, a case of an impaled cranial foreign body can be quite a challenge. The basic principles of stabilization, cervical spine immobilization, hemorrhage control and airway and wound care are important in initial management. Furthermore, as in this case, transfer to the nearest appropriate facility for definitive care is indicated.

Before transport, minimal manipulation of the foreign body is important, as underlying tissue may be damaged or hemorrhage recur. Protection of the injury site aids in the prevention of such manipulation. In this case, a standard paper cup placed over the impaled boat cleat served as an excellent protective covering. Tetanus prophylaxis

*The Trauma Score is a numerical grading system for establishing the severity of injury. The score is composed of the Glasgow Coma Scale and measurements of cardiopulmonary function. Each parameter is given a number (high for normal and low for impaired function). Severity of injury is estimated by summing the numbers. The lowest score is 1 and the highest is 16.

From the Department of Emergency Medicine and the Department of Surgery, Division of Neurosurgery, East Carolina University School of Medicine, Greenville 27834



Figure 2. Lateral radiograph of the skull showing the impaled boat cleat.

and antibiotic coverage are also indicated. Upon arrival to the appropriate facility, the patient should be completely

re-examined and prepared for the operative removal of the foreign object.

Preoperative evaluation may include plain radiographs, computerized tomographic scanning and angiography if injury to a major vascular structure is suspected. The object is then removed in the operating room where the physician is prepared to control hemorrhage and definitively treat the injury. Adequate débridement is absolutely necessary. Postoperative antibiotic and anticonvulsant coverage may be indicated.⁴

Acknowledgement

The authors thank Rosie Walsh for her assistance in the preparation of the manuscript.

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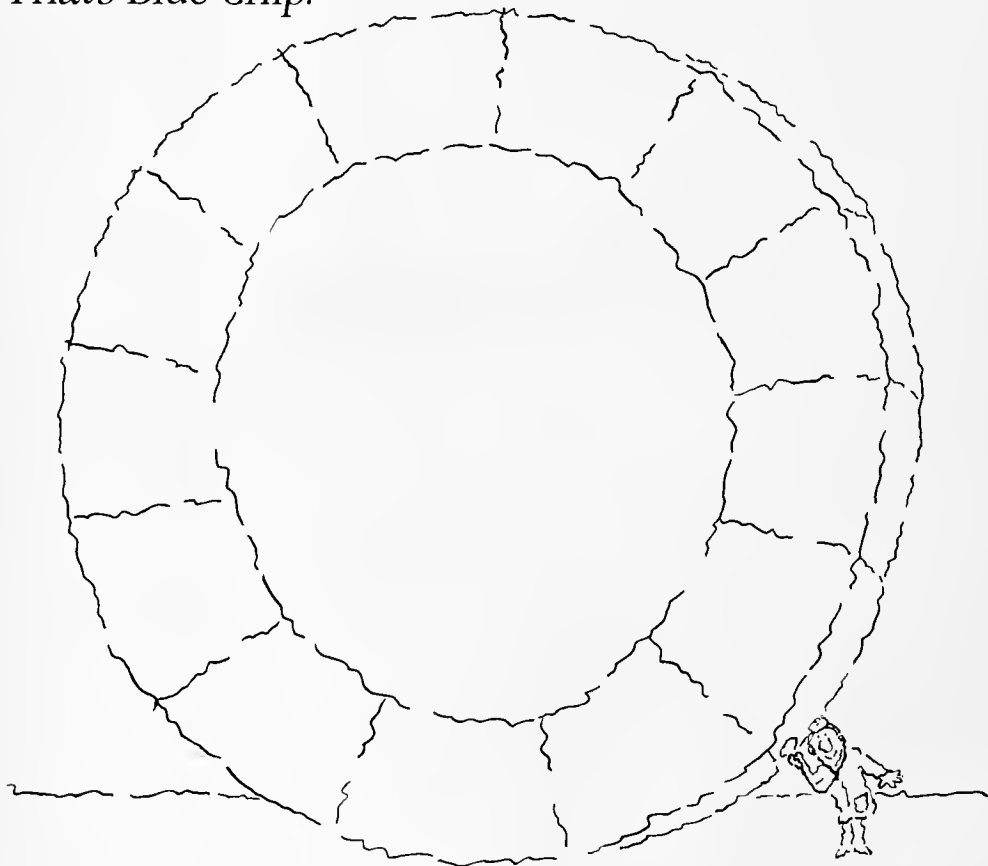
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Features for Patients

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Indoor Radon: A Residential Radiation Dilemma

Dayne H. Brown, M.S., Chief, Radiation Protection Section

In the past, inhalation of radon, a naturally occurring radioactive gas, and its radioactive decay products was recognized as a serious occupational hazard for uranium miners who, as a group, were observed to have a significantly increased incidence rate of lung cancer. This led to the development of Nuclear Regulatory Commission airborne radon standards for uranium mines.

Inhalation of radon and radon decay products by the public was initially recognized as a significant problem in western states where uranium mill tailings had been used as backfill and as a construction material in homes and public buildings. This led to a more general concern with technologically enhanced natural radioactivity, still focusing on things humans have done to cause increased radiation exposure above otherwise natural background levels.

It was not until 1984 that there was the belated realization that radon is the public's principal source of radiation exposure. This realization was triggered by a Pennsylvania nuclear power plant worker's setting off

personnel contamination monitor alarms when he reported for work. Subsequent investigation found his home to be highly contaminated, not with radioactivity from the nuclear plant, but with naturally occurring radon and its radioactive decay products.

Radon and Its Origin

Radon is a naturally occurring radioactive noble gas which is invisible, odorless, tasteless and chemically inert. It is interesting to note that if radon were not a gas there would not be an indoor radon problem, since it would remain fixed in the rock and soil where it originates and would not be able to migrate to the earth's surface and into the air.

There are actually three different isotopes of radon occurring naturally, each of which is radioactive: radon 219, radon 220 and radon 222. They are radioactive decay products of very long-lived, naturally occurring parents: uranium 235, thorium 232, and uranium 238, respectively. However, only one of them, radon 222 from uranium 238, is either produced in sufficient quantity or survives in a gaseous state long enough to actually migrate into the air from the rock or soil where it is generated.

Uranium, 99.27% of which is uranium 238, is present in nearly all soil and rock, sometimes in rather high concentrations. As uranium 238 atoms undergo radioactive decay, they emit radiation and are sequentially transformed into a series of different types of radioactive materials which also emit radiation, before eventually becoming nonradioactive lead. Radon 222 is one of the seventeen different radioisotopes resulting from this complex radioactive decay process.

Radon 222 has a radioactive half-life of about 3.8 days (time required for one-half of an initial amount to undergo radioactive decay). This is long enough to allow some of the radon, free from any chemical bonds, to migrate through the rock or soil into the air. The radon continues to undergo the radioactive decay process, giving rise to ten different types of nongaseous radioactive materials. It is the inhalation and subsequent lung deposits of these nongaseous radioactive "daughters" of radon which can cause significant radiation exposure.

Radon is constantly generated in the soil and rock formations and constantly rises to the surface of the earth where it mixes with air. In the out-

From the Department of Human Resources, Division of Facility Services, Raleigh 27603.

door air, radon is quickly diluted to very low (although easily measurable) levels. In general, these levels should not be of concern. However, inside homes or other enclosed structures over the ground, it is possible for radon to accumulate and concentrate as it emanates from the ground and into the enclosed air space.

Risk From Radon Inhalation

When inhaled, some of the radioactive decay products of radon are retained in the lungs where they cause radiation exposure to the bronchial epithelium. The only known health effect of this exposure is an increase in the risk of developing lung cancer.

In the absence of a nationwide survey, the national average indoor radon concentration has been estimated at one picocurie per liter (pCi/l). Continuous inhalation at this level is estimated to result in a radiation dose to the lungs of 3,500 millirem per year (mrem/yr) based on conversion factors used by the National Council on Radiation Protection, or a dose equal to about 80 chest x-rays. Scientists estimate that lifelong exposure to such a level will result in three to 13 lung cancer deaths per 1,000 persons exposed, and that between 5,000 and 20,000 people die each year due to radon-induced lung cancer.

The Environmental Protection Agency (EPA) has recommended that remedial steps to lower radon levels be taken in homes with concentrations over four pCi/l. Exposure at this level would correspond to an annual lung dose of about 14,000 mrem, equivalent to about 300 chest x-rays, and 13 to 50 lung cancer deaths per 1,000 people with lifetime exposure. This is in contrast to other standards set by EPA: 25 mrem/yr to the lungs, and most other organs, from nuclear fuel cycle facilities; 75 mrem/yr to the thyroid from nuclear fuel cycle facilities; and 4 mrem/yr to the total body or any organ from human-produced



radioactivity in drinking water. The significant difference between radon standards and other standards reflects a difference in philosophy made necessary by the widespread and natural occurrence of the problem. Even ambient levels in outdoor air may cause lung exposure on the order of 300 mrem/yr.

The radon levels in the home of the Pennsylvania nuclear plant worker who triggered the present concern were over 1,000 pCi/l. Of the homes surveyed in Pennsylvania's Reading Prong geological region, 60% exceeded the four pCi/l level at which EPA recommends remedial actions to reduce the level and 15% exceeded the National Regulatory Commission limit for uranium miners.

Representative data on radon in North Carolina homes are not yet available; however, data are available for about 160 homes that used radon measurement devices from the University of Pittsburgh. Of these, about 13% had levels above four pCi/l with a maximum of about 20 pCi/l. There was also some indication that levels may be highest in the western counties, somewhat lower in the central counties and lowest in the coastal counties.

As seen in the Reading Prong, local soil and geological features can lead to significantly higher concentrations of radon in homes. The University of North Carolina at Chapel Hill and the NC Department of Human Resources will conduct a cooperative statewide residential radon study this winter for the preliminary identification of potentially higher radon areas in North Carolina.

Help for Concerned Persons

Those who want to determine radon levels in their homes may purchase two different types of one-time-use measurement devices. Placed in the home for a period of time, the device is to be returned to the vendor for analysis and reporting of the average radon level that existed during that period. Such devices should cost between \$15 and \$50 each. Lists of vendors who passed voluntary EPA evaluations are available from the North Carolina Department of Human Resources.

The first type of measurement device is the *charcoal canister*. It has a useful life of only a few days and is most appropriate for those who need rapid results; for example, people planning to purchase a new home and wanting to know if there is a radon problem. Since radon levels may vary by more than a factor of 10 over days, weeks or months, the user runs a higher risk of false-positives and false-negatives with this device.

The second type is the *alpha track detector*. It has a useful life of several months and should not be used for less than two to four weeks. The resulting several-month average should yield a much better measure of the real average concentration of radon. This type is recommended for homeowners.

The following are general EPA guides based on measured radon levels:

200 pCi/l and higher: Take actions to reduce levels within several weeks and, if not possible, consider temporary relocation.

20 to 200 pCi/l: Take actions to reduce levels as soon as possible, but in no more than a few months.

4 to 20 pCi/l: Take actions to reduce levels within a few years, sooner if level is at the higher end of the range.

4 pCi/l and below: Reduction of levels in this range will be difficult and no specific recommendation is made.

An EPA pamphlet on radon reduction methods is available from the Department of Human Resources; however, the success of any one method will depend upon how the radon is actually entering the home. Since such methods can be expensive, it may be best to have technicians with sensitive real-time monitors identify the origin of the radon

and recommend specific corrective measures.

In the meantime, it should be emphasized that this is not a new health hazard, having existed far longer than humankind itself. The real questions are: How much of the non-smoking-related lung cancer may be due to indoor radon? Can we take

steps to reduce its previously accepted incidence rate?

Those who want pamphlets and advice on radon should call or write:

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Dental Implants

Ronald D. Baker, D.D.S., M.A., and David L. Koth, D.D.S., M.S.

Dental implants are devices placed into or upon the bony structures of the jaws to serve as support for tooth replacements. These replacements may be complete dentures secured in various manners to the underlying implant, which provides better retention and stability with enhanced chewing ability, or individual tooth replacements (crowns) or fixed bridges. Crowns and bridges may use the patient's own remaining natural teeth as well as the underlying implant for support.

Dental implants themselves may be divided into various types. Within each type there may be numerous design choices or systems available from various manufacturers. Implants may be made of pure metals, metal alloys, or ceramics, or combinations thereof. The metal which at present is thought to be most compatible with human tissues, offering the absolute minimal potential for rejection by the body, is titanium. The implants are either inserted into the jawbone or placed under the gum tissue where they rest on the bone of either jaw. The implants that are inserted into the jaw by making an opening into the bone and then placing the implant into the prepared space are known as endosteal implants. The implants that are placed underneath the tissue and on top of the bone are termed subperiosteal implants. With either type a portion of the implant usually referred to as a post will extend through the gum tissue into the mouth. There may be a variable number of posts depending on the circumstances of the case and the implant design.

Who Can Benefit from Implants?

Dental implants may be indicated for a number of patients, depending upon various psychological and physical conditions. It is recognized that there is a group of patients who, due to either emotional or psychological reasons, do not function satisfactorily with conventional removable full dentures. This may occur when the physical condition of the jaws and oral tissues would seem to be favorable for denture use.

There is a somewhat larger group of patients who have been able to wear conventional removable dentures satisfactorily for many years, but who have had continued loss of supporting bone and increasing difficulty with denture use. These patients do have viable alternatives. Bone grafts or synthetic bone may be used to build up the jaws. In many instances, soft-tissue procedures accomplished primarily or after bone buildup under general anesthesia in the hospital will allow these patients to again function with conventional dentures.

In many patients exhibiting bone loss and soft-tissue alteration, implants may be less invasive or traumatic than procedures to build up the jaws. Observation shows that in this group of patients post-menopausal women predominate. There has been no clear-cut correlation between the generalized osteoporosis or bone loss in these patients and loss of bone in the jaws. Dentures are associated with the potential for continued bone loss, and the rebuilt jaw will have the same risk of bone loss with dentures as the original jaw.

Although the potential for continued bone loss exists with some implant systems, there is very strong clinical evidence to show that se-

lected implant systems will actually provide physiologic stress to the remaining bone resulting in a marked reduction of bone loss. This applies to the lower jaw only; however, this is the jaw that usually presents with the greatest overall degree of bone loss.

Another indication for the use of implants is in the patient who has had a traumatic loss of bony and/or soft tissues in the mouth. Similar loss may be found in patients who have had tissue loss due to the removal of dental cysts or tumors, or who have had cancer surgery. One system in fact has a modified technique to place implants in either facial bones or skull bones to assist in the retention of maxillofacial prosthesis retention — i.e., artificial eyes, noses, and ears.

A significant number of patients with many lost natural teeth desire fixed replacements rather than removable appliances. In a case where there is inadequate support from the patient's remaining teeth, implants may be useful in providing the additional support required for the fixed replacement.

Implants are not the answer in all patients or in all otherwise unsolvable circumstances. Certainly the health history and medical consultation are exceedingly important in the evaluation of patients for the use of these devices. The patient must be in generally good health. Implants may not be indicated where there is systemic or local disease.

Implants have been accomplished in patients with systemic disease processes under medical control, such as a controlled diabetic. In the presence of either local soft-tissue or bony disease, the placement of implants should be delayed until the disease process has been controlled. In a case of surgical resolution of local soft-tis-

From The University of North Carolina, School of Dentistry, Dental Implant Program, Chapel Hill 27514

sue processes, three or four weeks of healing may be required prior to implant placement. In a case of bone disease, extraction of diseased teeth or teeth associated with local disease processes in the surrounding bone will require a delay of several months to allow for adequate bony healing prior to placement of the implant.

The patient must also be able to maintain the implant post and the surrounding tissues in a scrupulously clean condition. Indeed, the implant system may require more effort on the part of the patient than maintenance of natural teeth. Placing implants into the jaws of a patient who cannot or will not maintain them will almost certainly lead to failure.

Another consideration is the amount of bone and proximity to other anatomic structures. All endosteal implants require a minimum amount of bone for success. The amount required is dependent on the implant system utilized. If there is an inadequate amount of bone, consideration may be given to augmenting the existing bone with bone from the patient's hip (iliac crest) to allow implant placement.

Complications

Implants have provided exceptional service for a great number of patients. As with all surgical procedures, however, there are potential complications and failures. While all systems will invariably fail if the patient lives long enough, some systems have inherent properties that raise this potential at an early date.

The primary complication of concern to practitioner and patient alike is loss of the implant. This can occur early or after prolonged utilization in all implant systems; however, significant differences do exist among the various systems. One large group is designed for insertion followed by near immediate loading or placement in occlusal functioning (biting). In these systems, variably shaped bone preparations are made, followed by the placement of one or more implants with one or more posts

projecting into the oral cavity. The soft tissue is sutured around the post, but will not become attached to it. A dental appliance is then placed, supported by the implant post(s).

Since complete rigidity of the implant cannot be maintained during biting, the implant may have slight movement. This movement can cause the formation of fibrous connective tissue (scar) between the implant and the bone. Advocates of these systems relate this tissue functionally to the periodontal ligament attaching natural teeth to the bone. This is inaccurate in that there are cellular differences and scar tissue does not have a resistance to bacterial invasion. These systems then are subject to bacterial invasion of this peri implant tissue and eventually a localized osteomyelitis.

The time of occurrence and the extent of destruction of alveolar bone that will result in any one individual will depend on a number of factors. These include skill of the operator, host healing response, health, oral hygiene, time of recognition of the disease process, and time of removal of the implant. In many instances failure due to localized osteomyelitis has led to such significant degrees of bone loss that extensive bone grafting procedures failed to enable the use of conventional prostheses. Further implants were often not feasible. In the maxilla, bone loss and soft-tissue involvement have resulted in both oral antral and oral nasal fistula. These are often exceedingly difficult to close. They preclude the functional use of a conventional prosthesis because retentive suction cannot be secured.

Complications of this type are in general less severe with subperiosteal implants. The subperiosteal implant has achieved a longer-term success for many practitioners. The potential for osteomyelitis is less, since the bone is not primarily invaded in the placement process. Bone destruction may occur as the implant is at times seen to "settle" into the bone secondary to bone resorption from the

occlusal (biting) stress. Although rare, either of these circumstances can result in mandibular fracture. The primary complication with the subperiosteal implant system is the dehiscence (opening) of soft tissues over the implant framework. This, although not necessarily cause for removal of the implant, provides a potential irritant for the patient as well as a possible path for oral organisms to seed the peri implant area and cause infection.

The third major type of dental implant utilizes the concept of osseointegration. In this system, precision openings, usually cylindrical, are made into the bone. The cylindrical implant or fixture is placed in the bone, the surgical site is sutured closed and the implant is allowed to heal for four to six months before uncovering. In a second operative procedure posts are placed and the dental appliances fabricated. This system results in a soft-tissue capsule of minute dimension compared with the other endosteal systems. The surrounding soft tissue is so minimal that there is little potential for an infective process.

The most common complication of these implant systems is failure of the cylinder or fixture to become firmly attached to bone. Treatment for this is to remove the fixture and allow bone healing. As the failure is seldom accompanied by an infective process, another fixture can be placed in the same area. This is in sharp contrast with the destructive processes associated with failure in the other implant systems.

There are some complications common to all implant modalities. The complication often of immediate and prolonged concern is the loss of sensation or production of an altered sensation secondary to nerve damage. This most commonly occurs when implants are placed in the posterior part of the mandible causing injury to the nerve, which results in numbness or tingling in the lower lip and/or chin area. The lingual nerve to the

tongue or the infraorbital nerve are less commonly involved.

In the maxilla, the sinus is most commonly involved in the posterior area. Failure of the implant here may lead to an oral antral fistula secondary to bone loss. Oral nasal fistulae are also seen on occasion.

Failures secondary to infection may result in protracted periods of pain, facial or localized cellulitis, the risks of repeated courses of antibiotic therapy, and bone loss.

The incidence of complications may be more variable among dentists than in many other areas of practice because of the relative skill and training of the operator, patient selection and the systems used. The newer "osseointegrated" systems have a documented lower incidence of complications. Implants give many patients years of restoration to more normal chewing function. However, at this time there is not any one system with universal application and without some degree of complication.

Philosophy of Placement

In consideration of the above, it is clear that implant procedures must be accomplished by a person or team dedicated to following the meticulous procedures required at every step. The practitioner contemplating placing implants must have an understanding of the physical status of the patient and of how medical conditions may affect treatment. Since many implant procedures are accomplished on an outpatient basis, the ability to provide an adequate level of comfort by utilization of various sedatives and analgesics is important. Thus, practitioners accomplishing the implant surgery proper should have adequate knowledge, training, and skills in control of pain and anxiety. The surgical procedures must be done with a sterile technique approximating operating-room levels. The prosthetic rehabilitation accomplished on the implants must be done to exacting standards. Improper prosthetic procedures may cause failure of the fixtures.

As a result of these considerations, dental implants are being done in two widely differing manners. The first involves a team approach such as practiced by the Clinical Dental Implant Program at the University of North Carolina School of Dentistry. In this approach, the surgical placement is accomplished by a surgically trained dental specialist. The prosthetics is similarly accomplished by a dental specialist trained in prosthetics or a dentist with significant prosthetic experience. The area of dental implants is not a specialty area recognized by the American Dental Association. The second method of implant practice is by general dentists who have devoted significant effort to the area of dental implantology. Significant numbers of implants are accomplished by this type of practitioner.

The cost of a dental implant procedure is highly variable depending on the type of system utilized and the type of prosthetic replacement. Titanium is exceedingly expensive and presents difficulties in manufacturing. Single cylindrical implants or fixtures in one system cost approximately \$350 each, with five often being required for the full restoration of one jaw. When the surgical fee, the prosthetic lab, and the professional fee are added it should be appreciated that total expense to the patient may be in the realm of several thousands of dollars. In some instances simple stabilization of conventional dentures can be accomplished at more reasonable costs. Fixed bridges are usually much more expensive due to the higher costs of necessary lab work and gold used in these restorations.

Summary

Some specifically selected dental implants, when placed in appropriate, well-screened patients by competent and well-trained professionals, may provide years of excellent service with minimal complications. The traditional endosteal implants

may provide satisfactory service; however, they are not as predictable in outcome and do have documented greater degrees of complications. The subperiosteal implant has achieved a reasonable degree of success in the hands of many practitioners. It is appropriate only in a limited number of selected patients, and does have some variance of success dependent on the practitioner who places the implant. Newer techniques utilizing computer technology and ceramic coating may solve some of the disadvantages of this system. The newer osseointegrated systems have at this time the best documented success, with the least number and degree of complications. They are technically demanding. In addition, some of these systems do not have the flexibility to solve all conditions where implants may be desired.

The field of dental implantology is both complex and demanding. It is in an era of significant change, with increasing emphasis on basic and clinical research to further refine the usability and predictability of these systems. While not an answer for every patient or every problem, the contemporary dental implants can be expected to raise the quality of life for many dentally crippled patients.



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World Enough and Time — Hydrogen Sulfide Poisoning

Ronald B. Mack, M.D.

FOR most of us time is a thief that steals and steals until there is not enough left to do the things we want and need to do for ourselves. There is always another patient to see, a phone call to make, a committee meeting to attend, a problem with your children, and far too soon you are too close to the two-minute warning.

Andrew Marvell was an English politician in the 17th Century who worried about time and who is best remembered, by readers of poetry anthologies, for one poem: "To His Coy Mistress." In this delightful poem he implores his reluctant lady to make haste. He says, "Had we but world enough, and time, this coyness, lady, were no crime." Marvell later on in the poem admonishes his love: "But at my back I always hear Time's wingéd chariot hurrying near: and yonder all before us lie deserts of vast eternity." If you are ever confronted by a patient with hydrogen sulfide (H_2S) poisoning you will not have time to do extensive contemplation — you will have to act or the patient will no longer answer "here" in the roll call of life. Marvell suggests, "The grave's a fine and private place but none, I think, do there embrace."

All of you know what hydrogen sulfide gas smells like, that's right, *rotten eggs*. This very noxious substance is colorless and highly flammable. The characteristic odor is perceived at relatively low concentrations but at somewhat higher concentrations the olfactory receptors apparently become paralyzed and the odor does not act as a danger signal because you can't sniff it properly (oh, how I wish for olfactory paralysis, at times, in our clinic; some of the parents who come to the ambulatory department suffer the disease known well to outpatient clinic physicians, "pit rot"). The range of toxicity of H_2S can be as little as experiencing eye irritation and cough to *immediate death*.

Exposure to hydrogen sulfide gas can occur in a variety of settings such as mines, sewers, waste-water treatment plants, in the petrochemical, gas and tanning industries and in liquid manure systems² (ick!!) kept in storage tanks by livestock farmers. Hydrogen sulfide gas is very toxic, odoriferous, extremely irritating, inflammable and colorless. The toxic effects are both local and systemic.

The local effects of H_2S seem to be particularly difficult on the eyes of the victim, causing intense conjunctival infection, ocular pain, blurred vision, blepharospasm, lacrimation, photophobia, keratoconjunctivitis, vesiculation

of the corneal epithelium and the sensation of seeing colored halos around lights. Under these circumstances it would be very difficult to say those famous lines from "Casablanca" that Humphrey Bogart said to Ingrid Bergman: "Here's looking at you kid!!" By the way, because exposure to high concentrations of this gas can be fatal, maybe the experience of seeing colored halos is a real "out of body" event in those destined for heaven (I must admit I never knew angels wore colored halos; well, live and learn, or is it, die and learn?) Mucous membrane involvement, other than ocular, is to be expected, especially rhinitis, pharyngitis and irritation of the tracheobronchial tree. It would not be a surprise, in the exposed patient, for the doctor to observe severe coughing and dyspnea in addition to pronounced ocular disability.

Let the record show that at higher concentrations hydrogen sulfide gas can kill you dead and quickly. It can, in fact, kill as quickly as cyanide if the concentration is high enough. Patients, still conscious after exposure to high concentrations, complain of headache, nausea, dizziness, confusion, and weakness of the arms and legs, and then they can abruptly lapse into unconsciousness and death due to respiratory failure. There seems to be a direct depressant effect on the respiratory center caused by this gas. The mortality rate is about 6%. In a patient who is still alive but obtunded you would expect to see cyanosis, tachycardia, tremors and seizures and you often do see these adversities, but be careful or you may be the next victim. *Let it be understood that the health care professional offering aid to the victim must never go to the site of the downed victim without wearing a self-contained breathing device.*³ If you ignore this warning, do so at your peril. Hearing the bugler blow "TAPS" is not my idea of a fun afternoon. The majority of deaths due to this poison occur at the exposure site. Rescuers apparently have a high morbidity and mortality rate.

It is fair to ask, at this juncture, why hydrogen sulfide gas is so toxic. This gas is an intracellular poison. It causes histoxic anoxia and anyone who has had this condition can tell you that it smarts. The hydrosulfide, according to many authorities, inhibits the cytochrome oxidase system (as does cyanide) by interrupting electron transport. The end result is cell death because of the inactivation of aerobic metabolism. It is no surprise that the brain and heart are the organs most sensitive to oxygen deprivation.

It is probably old news that many treatments are controversial. All one can do when the truth is not exact is

From the Department of Pediatrics, Bowman Gray School of Medicine, Wake Forest University, Winston-Salem 27103.

to go with experience, good clinical judgment and the best data available. One must be reminded of the fact that treatment must be quite rapid and includes as a primary precept that the victim must be removed from the toxic site with great dispatch (observing the safety precautions for the rescuers previously mentioned). The basic controversy regarding treatment is whether the *use of nitrites* is indicated. Because this gas inhibits cytochrome oxidase it has been the practice to treat this poisoning as one would treat a cyanide poisoning, i.e., administer nitrites. This latter substance has as its aim the inactivation of sulfide. Nitrites attempt to do this by: (1) *forming dissociable sulphemoglobin* which allegedly removes sulfide from combining in tissue (the now nontoxic sulphemoglobin is further broken down into nontoxic oxidized forms of sulfur and excreted in the urine) and (2) *inducing methemoglobinemia* which competitively binds circulating sulfide ions, removing it from the cytochrome oxidase system. Does this methemoglobinemia formation as a treatment sound familiar? Sure it does. Antidotal induction of methemoglobinemia is the basis of the treatment of cyanide poisoning, i.e., methemoglobin has a greater affinity for cyanide than does cytochrome oxidase. The end result of the treatment of cyanide poisoning is to disrupt the cyanide-cytochrome complex, allowing oxidative metabolism to resume.

We can now see what we have to do to reverse the bad situation in a hydrogen sulfide poisoning as quickly and efficiently as we can: 100% O₂ must be administered. Begin nitrite therapy. Where are you going to get this stuff? You mean you forgot already? You get it from the Lilly Cyanide Antidote Kit. Begin with the amyl nitrite ampules. After breaking the ampule, administer the amyl nitrite in such a way that the patient inhales it for 30 seconds of every minute. Use a fresh ampule every three minutes. Only give the amyl nitrite until the sodium nitrite has been prepared for intravenous administration. The dosage schedule for the sodium nitrite is the same as in cyanide poisoning. Be very careful when administering sodium

nitrite to children as it can lead to fatal methemoglobinemia. For children you can give a 3% sodium nitrite solution at 0.33 ml/kg not to exceed 10 ml at a rate of not more than 2.5 to 5.0 ml per minute. The lower the children's hemoglobin the less sodium nitrite you should administer. Oops, don't forget . . . do not administer sodium thiosulfate in H₂S poisoning as you would in cyanide intoxication.

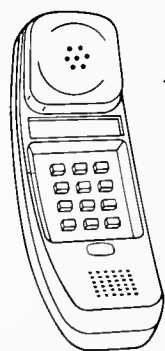
Well, that seems easy enough, doesn't it? Wrong, rotten egg breath!! The issue of nitrite therapy in this intoxication is far from settled and is, in fact, rather controversial.⁴ However, because it is currently the only game in town, induction of methemoglobinemia is recommended, if the treatment can be started early. Several authors prefer oxygen therapy alone without nitrite therapy, because sulfide is rapidly oxidized to sulfur and sulfur oxides by giving oxygen therapy and producing oxyhemoglobin and because methemoglobinemia production takes too long and could be dangerous.⁵ Some authorities go a step further and administer hyperbaric oxygen, which seems like a great idea. Until a better treatment is found the use of nitrites is probably the way to go.

I could not find any evidence that Marvell's coy mistress succumbed to his entreaties but there is a footnote in one source that says he was awaiting the results of a HTLV screen.

Please say hello to my new grandson, Joseph Andrew Mack, who is giving us a problem — we can't get the fettuccine noodles small enough to fit through the nipple holes in his bottle.

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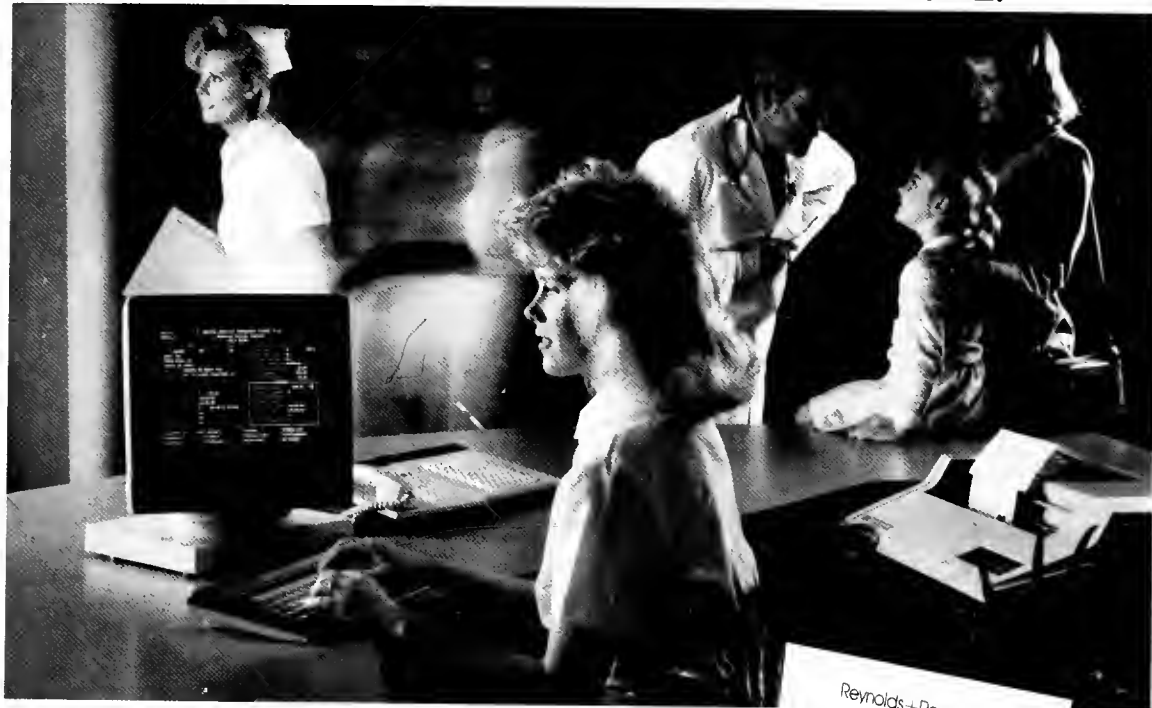
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The Boat People

The 1986 Whitehead Lecture to the 1990 Class of the University of North Carolina Medical School

Ernest Craig, M.D., Henry A. Foscue Distinguished Professor of Cardiology, August 20, 1986

PEOPLE will look back on this as being a time of great ferment and change in the delivery of health care, and many of the profound alterations that we are witnessing are only marginally under the control of our profession.

What has happened is that the cost of medical care has risen so dramatically and out of proportion to other costs in society that various methods of containment have had to be inaugurated in an effort to bring the whole thing under control. So we see a proliferation of new schemes by which health care is provided with various incentives or restrictions designed to shorten hospital stay, reduce unnecessary laboratory work, duplication of diagnostic procedures and un-needed surgery. All of these, of course, are admirable goals. The forms that these cost-containing methods take are numerous and bewildering so that patients are confused about where to sign up in the hopes of finding humane and scientifically expert medical care.

This confusion on the part of the public is shared by the medical profession itself, as I have suggested in this drawing, whence comes the title of my talk — "The Boat People."

The boats are the new vehicles for delivery of health care: the Health Maintenance Organization or HMO; the Preferred Provider Organization or PPO; Blue Cross/Blue Shield; Electronic Data Systems or EDS; Diagnostic Related Groups or DRGs; for-profit hospitals which may buy out community hospitals and take over the obligations formerly assumed by the county; independent surgical clinics; doctors in supermarkets ("doc in a box"); and finally a traditional solo practitioner. These alternatives confront the medical profession, faculty, and those in practice, nurses and paramedical professionals, patients and general public.

We see the Class of '90 in the midst of this gang — relatively unperturbed by the chaotic scene around them. This is because their minds are not cluttered by earlier experiences which make the current situation so radically different for these other players. The doctors in practice are deeply disturbed. This one has decided to call it quits and go over the side. His colleague is reaching out, perhaps to save him, or is he actually giving him a push? On the horizon lurks a ship full of lawyers ready to scoop up any strays. The people on the dock, which includes all of us, don't know where these boats will be taking them. Unclear

about their objectives and the means of getting there, they resemble the boat people setting out from Vietnam to some uncertain destination.

Each of these vehicles for the delivery of health care has the potential of helping to accomplish the overall objective of excellent care under controlled cost. The problems with them are too varied and complex to discuss here but generally result from the possibility of failure to reach the intended purpose, owing to human frailties of avarice, excessive bureaucracy, etc. Conflicts of interest arise where the decision-making on the part of the physician is leaned on by a variety of financial and administrative influences. A potential sinister result of all this is a two-platoon health care system with the poorer segment of society left out.

In this turbulent setting, then, how is the Class of '90 going to keep its bearings and exert its hoped-for leadership in the coming century?

Obviously the star by which these newest of the boat people, the Class of '90, will hopefully set their compasses is what is best for the patient. This seems too obvious to mention, but it requires reiteration. A fixation on the well-being of the individual patient is an admirable goal but is probably an oversimplification. There is also to be considered one's concern with what may be a conflicting duty to society as a whole. For example, the media are frequently giving details of the perilous experience of some child in Texas or California undergoing a liver transplant, or a man in Louisville getting a mechanical heart. The public appears to have an insatiable interest and faith in these technological advances. The liver transplant may be rejected and require an emergency search for a second donor. Even the President has intervened in one such drama. The cost of such procedures is enormous. Since resources are finite, we will have to weigh the projected benefits against the use of the money in less dramatic ways for the benefit of a larger number of people.

It is clear that in the foreseeable future any measurable improvement in the health of the population is going to have to take place by means of preventive medicine and reduction of self-destructive, suicidal practices and not by means of individual technological spectacles. I have in mind the reduction of toxins in the atmosphere, the arms race, for example, being the world-class suicidal impulse, against which I'm proud to say members of our faculty and physicians all over the world have provided an imaginative and courageous campaign. Other destructive tox-



Ernest Craigie

ins like drugs, cigarettes and alcohol need to be combatted starting at the school level. Other major problems such as obesity, which afflicts one-third of our population, teenage pregnancy, inadequate pre-natal care, malnutrition in school children — all of these are preventable problems in which our profession must take a leadership role.

At this juncture in medical history, I think that you are particularly fortunate to be the first-year class at the University of North Carolina, rather than at one of many other equally prestigious schools, because the University — that is, the entire University — has always acknowledged its responsibility to all the citizens, regarding the whole state as its campus. The planners of the present four-year medical school back in the late '40s recognized the applicability of this historic obligation to the new institution. Built into its charter was the stated intention of bringing better health care to all of North Carolina.

For those of us privileged to participate in the care of patients here, research and teaching, these years have been very gratifying, since we have been permitted to provide exemplary care to all those referred to our doors regardless of financial status, color, or other potential barriers. We have observed the quality of care all over the state going up dramatically thanks to the effective role of our graduates and those of other neighboring schools. An additional remarkable achievement has been the establishment of our Area Health Education Centers, or AHECs, located in a dozen places from Asheville to Wilmington and in constant personal communication with the center here by means of a fleet of small airplanes.

I don't have any precise itinerary to propose for those embarking on the boats in these times of uncertainty; however, I am encouraged by the idealistic and yet pragmatic approach to patient care problems manifested by our students, and fostered by the philosophy of the University as a whole through its faculty. This is exemplified better than I can say in a brief essay which one of our current fourth-year students, Susan Hovey, wrote in connection with her application for internship. (A statement of purpose is required with the application and generally it summarizes noteworthy experiences the student has had to date and aspirations for the future).

She writes as follows regarding an experience on her first clinical rotation in the third year:

"My feelings about patient care came to the forefront one day as a result of a very simple incident. I watched an old fragile arthritic patient moving from bed to wheel chair with the assistance of her husband who was only slightly more robust. Although the scene was in a way painful, it also seemed more human, real and therefore graceful than anything I had ever seen. This year I have come to value the patients immensely. They have been an unceasing source of solace and inspiration for me. I was especially and unexpectedly attracted to the older patients and found myself choosing to spend time with them beyond the necessary. I feel a responsibility to these people and in caring for them, hope to have a career that I will both respect and enjoy."

Another valuable discovery that Miss Hovey has made is the importance of maintaining a lively interest in hobbies or nonmedical cultural activities. This helps to prevent medical tunnel vision and improves one's equanimity in a stressful occupation. A broad cultural background is also of immense value in establishing an empathetic relationship with patients.

I recall a vivid example of this from my own intern days some 43 years ago. In a hospital in Boston I had the privilege of having as one of my attending physicians a wise man named Chester Jones. The other intern on the ward and I had under our care an elderly gentleman with a severe anemia. Some malignant condition had destroyed his bone marrow where red blood cells and other formed elements in the blood are manufactured, and he had become terribly anemic. We measured his hemoglobin every day from blood samples obtained by pricking his finger. We knew that the only way his life could be prolonged was by blood transfusions, and he received one or two of these with only transitory benefit. His mind was quite clear. He knew that he was dying, but he refused to have any further transfusions. We had reached an impasse. We told him that we were going to refer the matter to our attending physician, Dr. Jones, since we had confidence that his superior authority and persuasiveness would win the day in behalf of our diagnostic and therapeutic intentions. So before rounds next morning, as was our custom, we filled Dr. Jones in on the events of the preceding night and the crisis that we had reached with this particular patient. Then we went from one bed to another around the large ward.

As we approached the bed of the anemic gentleman, I could see that he was the color (white) of his tunic that

was supplied by the hospital. His jaw was thrust forward in a grim determined manner, and his toothless mouth formed an inverted U. All of his belongings and clothing had been taken from him and were stored elsewhere so that the only fragment of personal possessions remaining was a catalogue of Jackson & Perkins, the rose company, lying on his bedside table.

Dr. Jones picked up the catalogue and said, "What do you think of this year's prizewinner, Double Delight?" With that the old man's mouth cracked up into a big smile. Dr. Jones sat down and for five or ten minutes they had an animated discussion about roses. Then we went on to the next bed and shortly rounds were over. Afterwards the other intern and I and the resident had a hurried conference.

"What was decided about the transfusions?"

"I didn't hear them say anything about it!"

The resident said: "It was all decided."

They understood each other perfectly, and realized that further interventions would be futile.

So there won't be any more transfusions.

There won't be any more finger stickings.

Dr. Jones perceived that the time had come to discontinue our "scientific" efforts and devote ourselves to making the remaining hours or days of this patient more tolerable, and he was demonstrating to us how this might be done.

I'm sure that you will have similar experiences — some frustrating, many gratifying. I feel confident that the interaction of your class with our splendid faculty and with the patients whom you will meet will result in increasing maturity, judgment and leadership from which will emerge satisfactory solutions to the problems of health care in the 21st Century. ☐

\$50,000 Award for Innovation

Pfizer Hospital Products Group has posted a \$50,000 "Award for Innovation" in medical devices. The Award will recognize an individual or research team for excellence in medical device innovation and encourages further research and development of medical devices to manage and treat diseases. This is the first time the Award is being offered and any person in a health care-related field is eligible to submit an entry.

"An outside panel of experts will judge the scientific merit of the invention, and its benefit to patients," said George Flouty, M.D., medical director of Pfizer Hospital Products Group. "Also evaluated will be the practical application of the invention and its possible impact on the quality of health care."

The deadline for applications is January 30, 1987, and the Award recipient will be announced in May 1987. Application information may be obtained by writing to:

George Flouty, M.D.
Pfizer Hospital Products Group
235 East 42nd Street
New York, NY 10017
Attn: Award for Innovation

What I Learned from a Pregnant Teenage Diabetic Patient

Robert P. Schwartz, M.D.

SHE was 17 years old, and had been my patient for seven years. I first saw her at age nine years, when she came to my office with growth failure and classic signs and symptoms of hypothyroidism secondary to Hashimoto's thyroiditis. After treatment with thyroxine, she had a rapid growth spurt. Since nine months of age, she had been on insulin for Type 1 diabetes mellitus.

Diabetic control was difficult during the teen years, and her glycosylated hemoglobin values were elevated. After 16 years of diabetes, she developed background retinopathy with scattered microaneurysms and hypertension.

On a visit at age 16½ years, the patient's mother pulled me aside to tell me that her daughter had a boyfriend, was sexually active, and was having unprotected intercourse. The parents were both distraught, but wanted me to talk with her and prescribe a contraceptive. I discussed the various types of contraception with the patient, telling her that birth control pills would place her at increased risk of additional vascular complications because of her diabetic retinopathy and elevated blood pressure. I referred


her to a gynecology colleague who also was reluctant to prescribe oral contraceptives because of her retinopathy. He recommended a diaphragm, which she refused. As an alternative, he urged her to use an intrauterine device; again she refused. The boyfriend, who had dropped out of school in the eleventh grade and was working as an auto mechanic, was not willing to use condoms. The patient continued to date this boy. One year later, she was pregnant and had an abortion.

Teenage pregnancy is an epidemic. There were 24,848 teenage pregnancies in North Carolina in 1984 — fifth in the nation. These teens don't plan to get pregnant. The problem is that they don't plan at all.

This case taught me that we must take the time to take sexual histories on our patients early in adolescence. We should check their fund, or lack, of knowledge, and counsel them on the danger of unprotected intercourse. For sexually active high-risk patients, we must consider both the side effects of an oral contraceptive and the risk of an unwanted pregnancy.

Recently, another one of my teenage diabetic patients told me that she was sexually active, and she asked for birth control pills. I thanked her for telling me; and without any hesitation, I gave her a prescription.

From the Department of Pediatrics, Charlotte Memorial Hospital & Medical Center, and the Charlotte Area Health Education Center, Charlotte 28232-2861.



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Physicians as Science Writers

John M. Falletta, M.D.

ISAAC Asimov presented an intriguing notion in his address, "Future of Medical Communication, Doctors and People Talking."¹ He suggested that someday physicians in medical research would be doing their own experiments much as they do today, but that the manuscripts reporting their research would be prepared by a science writer. This view may not be of interest to those physicians whose measure of success excludes the quality and length of their bibliography. But for those of us who report the results of research projects and who find the process of manuscript preparation painful and laborious, this idea merits further consideration. Freedom from the effort of scientific writing could lead to two favorable results: the physician would have more time for discovery; and the manuscript might be more readable. This essay addresses the latter.

The merits of having a science writer to help with medical writing have been embraced by a variety of physicians. Indeed, several hospitals and research institutions now employ such a specialist. An example of how such a colleague could be helpful to the investigator was published several years ago in the *New England Journal of Medicine*.² Dr. F.J. Ingelfinger, who was then the editor, arranged for an article on tumor immunology to be rewritten by Barbara Culliton, a writer for *Science*. The article dealt with some immunologic phenomena detected in cells from patients with acute leukemia.

From the original manuscript:

"The present study confirms previous observations that the lymphocytes of the majority of patients with acute leukemia can mount a blastogenic response to their own leukemia cells. Although a correlation between lymphocyte response to autologous leukemia cells and the clinical status of the patient was not reported in these earlier studies, the current studies demonstrate a strong correlation between the degree of blastogenic response to acute myelogenous leukemia cells and their response to treatment, e.g., the higher the stimulation index, the greater the chance for a chemotherapy induced remission. We have previously demonstrated that one can relate prognosis of the patient with acute leukemia to degree of general immunocompetence."³

Now from Culliton's revision:

"Our results support the view that one can correlate specific features of the cell mediated and humoral immune systems with prognosis in acute leukemia. Generally, the correlation we find pertains to individuals with acute myelogenous leukemia rather than to those with acute lymphoblastic leukemia. Our results also confirm previous observations that a majority of patients have lymphocytes capable of mounting a blastogenic response to their own leukemia cells."⁴

While it may be difficult to make a precise comparison between the two versions if one is unfamiliar with cellular immunology, clearly the revised version is shorter, probably more easily understood, and definitely is less ponderous and more enjoyable to read. However, this does not prove that Asimov's prediction will ever come to reality, or that it should. As Dr. Ingelfinger pointed out, a science writer's task of reworking a journal article is far from easy.² Assuming that the rewriting is limited to the ideas expressed in the original paper, the science writer becomes more of a translator than an independent author. A methods section, which is usually already written in a concise and simple style, does not lend itself easily to rewriting. Also, the science writer cannot be expected to present a clear and abbreviated description of work when the bulk of the work is so preliminary as to preclude the development of any precise conclusions.

The assessment of whether the rewritten manuscript was worth the effort and expense involved was something that Dr. Ingelfinger properly left to each investigator. Were we to have a Barbara Culliton at our elbow, ready to revise our ponderous first draft into luster and fluidity and instant acceptance, and were we to have independent funding to support her work, probably all physician-writers would welcome her assistance. Each might also breathe a sigh of relief that the ostensible rate limiting step to success, at least in the academic world, had been overcome. But partly because of financial realities, partly because our egos encourage us to say it our own way, and partly because we require precision in the reporting of our data which a science writer might not achieve, the vast majority of us will continue to be responsible for our own writing of scientific manuscripts, and some of us may even enjoy that requirement.

How can physicians themselves, who have a poor reputation as writers, achieve clarity and simplicity in medical writing? Is there something inherent in the scientific method that makes the report of research conclusions necessarily

From Department of Pediatrics, Division of Hematology/Oncology, Duke University Medical Center, Box 2916, Durham 27710.

dull, verbose, or awkward? Clearly the answer is "no"; there are many examples to be found of crisp, concise and enjoyable scientific prose covering a wide range of topics. A few sentences taken from Watson and Crick's letter to *Nature*, in which they first described the double helix, illustrate how elegance in discovery can be matched by simplicity in prose:

"We wish to suggest a structure for the salt of deoxy-ribose nucleic acid (DNA). This structure has novel features which are of considerable biological interest. . . . It has not escaped our notice that the specific pairing we have postulated immediately suggests a possible copying mechanism for the genetic material."⁵

One might consider that work leading to the Nobel Prize ought to be well written! But good writing can even be discovered among less profound biological observations. North Carolinians McMillan and Purcell have written about the puss caterpillar, alias wooly worm, describing its characteristics and the hazard that it holds for human health:

"Among both physicians and the lay public a vague, if not specified awareness of caterpillars probably exists. In this connection, and with summer and its varied fauna at hand, it seems appropriate to point out that caterpillars of more than 50 species possess irritative hairs. Depending upon the species, the effects of the hairs range from a local dermatitis to an alarming, if not frankly dangerous, disorder with systemic signs and symptoms.

"Although the caterpillar is known to exist widely in the southern United States, Texas apparently harbors the greatest number, and it is therefore appropriate that most clinical reports have come from that state.

"The purpose of this report is to affirm the presence of puss caterpillars in North Carolina, to describe the effects of its hair stings and to consider briefly the general problem of irritative caterpillar hairs. At the outset it seems well to point out that although Texas appears to have more puss caterpillars than any other state in the union, there is no evidence that the average caterpillar in Texas is larger or worse than the average in other states, including North Carolina.

"Although caterpillars in general and the puss caterpillar in particular hardly constitute a major health menace to the American scene, they probably constitute a sufficiently bothersome and unfamiliar problem to justify directing attention to them. What is even more provocative than the clinical effects of caterpillar contact is the unanswered mechanism of their hairs and the undetermined evolutionary basis for the varied defense mechanisms that these hairs represent. Indeed, the not so friendly puss caterpillar, alias wooly worm, is formidably equipped against man."⁶

These excerpts from a manuscript published in a leading American medical journal relate to a subject which most physicians would not have dared to investigate, let alone

prepare for publication. The manuscript illustrates vividly how even an obscure topic can be presented well.

Is it possible to analyze medical writing so as to identify common weaknesses? Probably not without dealing with rather dry, pedantic concepts. The usual weaknesses encountered in bad medical writing are overlong sentences, insufficient verbs, reliance on the passive voice, and excessive use of prepositions.

Concerning prepositions and the passive voice, here is an example: "In a previous paper concerning neuritis occurring after insect stings, a patient was described in whom papilledema developed in the left eye within two weeks after being stung on the left temple by a bee."⁷

By changing the passive voice to active, one can transform the sentence to: "In a previous paper, which discussed the neuritis following insect stings, we described a patient in whose left eye papilledema developed within two weeks after a bee sting on the left temple." While the sentence is not shortened much, four prepositions have been eliminated along with the passive voice, and the sentence flows more smoothly.⁷

Efforts at simplicity and brevity have taken some interesting turns. During the 1930s, British linguist C.K. Ogden reduced conversational English to 850 basic words and called his system "Basic English."⁸ He reduced the vocabulary of nouns to 600, adjectives to 150, and structural words — verbs, pronouns, adverbs — to 100. His most remarkable economy of words occurred by limiting verbs to 16 — come, go, get, give, keep, let, make, put, seem, take, be, do, have, say, see, and send, plus may and will. By using combinations of verbs with prepositions or nouns, Ogden was able to retain clear and vivid prose, plus simplicity. "Enter" became "go in," "prepare" became "get ready," and "hurt" became "give pain."

His system of Basic English was not intended to substitute for conventional English in circumstances in which persuasive or imaginative uses of language are appropriate. The Lord's Prayer, the Psalms, and most poetry would likely lose considerable power if translated into Basic English.

So would much scientific prose lose its power. The common thread that distinguishes good writing includes simplicity and the active voice. When a simple word can substitute for a complicated one, opt for the simple; and keep in mind that active statements are far preferable to passive statements. "I investigated several examples of good writing" is certainly better than "several examples of good writing were investigated by me."

When we write, each of us is a teacher as well as a student. If clear communication is important, then we have an obligation to practice careful writing and to insist upon the same from our associates.

For example, do not submit a preliminary draft of a manuscript to a colleague for review until you have polished its construction and given it your best effort. When reviewing a colleague's manuscript, offer suggestions to achieve clarity and brevity, and explain why your changes seem preferable. As a journal reviewer, do not accept manuscripts that are sloppily written without requiring their revision. As a journal editor, set clear standards of excellence for medical writing. Remind contributors that their

work will probably draw more attention if it is presented well.

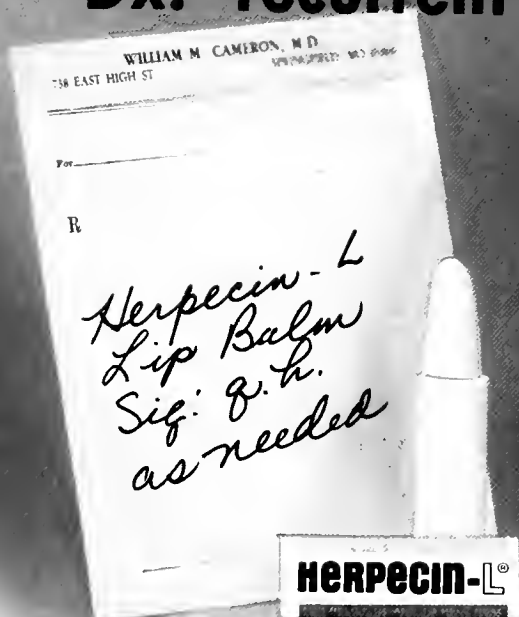
Not all of us have the talents of a science writer, and many of us do not review manuscripts for medical journals, much less edit them. But we can have standards for writing as if we did!

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Letters to the Editor

To the Managing Editor:

Thank you so much for your assistance in starting the ball rolling in my quest to report the work of Sugarman and Butters (Jeremy Sugarman and Ronald R. Butters, *Understanding the Patient: Medical Words the Doctor May Not Know*, 1985;46:415-7; and letter to the editor, 1985;46:679). I have written to Dr. Sugarman for his permission — and have sent him a copy of the November issue of *Geriatric & Residential Care News*.

And thank you so much for sending the *Journal* and the latest news on medical malapropisms and slang. As I read the lists in complete form, almost all were quite familiar and also conjured up the faces and names of those who used the terms frequently.

You should also know that I am reading *all* of the articles in your journal, and I enjoy them very much. I find retirement an "absolutely, positively" exciting time of life. In addition to the newsletter, I translate German medical journals for those who don't read the language, write scripts for teaching cassettes in several areas, am writing a several-volume set of books on the history of Spaniels, and am failing miserably in trying to conquer the physics and mathematics necessary to understand the current excitement over the origin of the universe.

Frances Greer, Ph.D.
Geriatric & Residential Care News
Editorial Office
P.O. Box 938
Del Valle, TX 78617

To the Editor:

I am delighted with my article "Horseback Riding in North Carolina" that appears in the November 1986 NCMJ (47:530-3). I thank you and Laurel Ferejohn (Managing Editor) for your encouragement and help.

I hope that your medical readers find it of assistance. I shall make the contacts with the horse community for their awareness of its availability through their physicians. I shall take it to the Haywood Trails Riders, the local horse club in which I am active, when I show the videotape "Equestrian Helmet Safety."

Thank you again for your leadership in North Carolina.

Doris Bixby Hammett, M.D.
Co-Chair, American Medical Equestrian Association
103 Surrey Road
Waynesville 28786

Some Comments on Dr. Crist's Article

To the Editor:

I am writing to protest and request a printed apology for the editorial published in the November, 1986, *North Carolina Medical Journal*, by Dr. Crist, et al (*Sobering Thoughts*;47:511). We are all entitled to our opinions, but for a diatribe of this type to appear as editorial comment in a respected medical journal, which we as the members of the medical society pay for, is an affront to the dignity

and the intelligence of the readers of this journal.

It is difficult for me to believe that an article of this type expresses feelings of the Editorial Board of this journal, and I would suggest that in the future greater care be taken in publishing opinions of a small select group as representing the editorial philosophy of this journal.

D.G. Joyce, M.D.
Mecklenburg Orthopedic Associates, P.A.
Suite 103 Randolph Building
Randolph Medical Park
3535 Randolph Road
Charlotte 28211

To the Editor:

After reading the *North Carolina Medical Journal* editorial titled "Sobering Thoughts," I at first felt anger and then shame. Shame that such a blatant anti-Catholic cacophony of words could be published as the opinion of the editors of the *Journal* of my State Medical Society. I was under the impression that the *Journal* was a scientific publication dedicated to the exchange of ideas and the search for truth.

This inflammatory, irresponsible, Vatican baiting editorial written by Takey Crist et al does not warrant the effort of refutation. A bigot is a bigot and no matter how hard one tries, certain minds remain closed.

I certainly think the *Journal* owes an apology not only to each and every Catholic among its readership, but to every moral man and woman. In addition, unless the anti-Catholic stance of your editorial is the official policy of your publication, a retraction is mandatory.

Stephen J. Naso, Jr., M.D.
Mecklenburg Surgical Associates, P.A.
Hand Surgery and Rehabilitation Center
2039 Randolph Road
Charlotte 29208

To the Editor:

A fellow physician, Dr. Stephen Naso, recently responded to the *Journal's* editorial titled "Sobering Thoughts." We would like to concur with Dr. Naso's remarks concerning the blatant anti-Catholic opinion of the article.

We certainly feel that if the author is as he says "dedicated to caring for women," the caring for women of other opinions and beliefs should be of equal importance.

William H. Shaia, M.D.P.A.
George L. Raad, M.D.
2125 Berryhill Road
Charlotte 28208

To the Editor:

I am disappointed with the editorial, "Sobering Thoughts," in the November *Journal*. I came away from reading it with a bad taste in my mouth. Most definitely there are anti-Catholic overtones present. The authors are no better than those they chastize with their dictatorial and

angry statement that "we must rid our government of those

The viewpoints expressed in the editorial are as one-sided as the factions they criticize. I consider "Sobering Thoughts" an affront to the intelligence of the *Journal's* readers. The authors should have kept their biases and bigotry to themselves.

Frederick J. Bachl, M.D.
Salisbury Children's Clinic, P.A.
720 Grove St.
Salisbury 28144

To the Editor:

I have been a member of the N.C. Medical Society and a reader of its *Journal* since my arrival in this wonderful state in 1970. I have never read a more thoroughly political nor blatantly bigoted editorial than the one (by Crist, et al) found on page 511 of the November 1986 issue.

In an otherwise fine publication I object to its inclusion and don't understand what you hoped to accomplish in printing such inflammatory, one-sided opinion. By stimulating temper you inhibit reason and so become part of the problem. Will you now bring balance to the argument by permitting an opposing view to be published?

Philip Palmer Smith, M.D.
1810 Azalea Drive
Wilmington 28403

To the Editor:

As Bishop of the Roman Catholic Diocese of Charlotte, I am appalled by the apparent anti-Catholicism of the editorial, "Sobering Thoughts," in the November issue of the *North Carolina Medical Journal*. The fact that it appeared as an editorial and not as a letter to the editor, or as an expression of the opinion of the authors, leads me to question whether it does, in fact, represent the official position of the North Carolina Medical Society. I trust that it does not.

I am disturbed that the authors of the editorial used a matter completely unrelated to the Catholic Church as a springboard for an attack on the Church. Neither G.D. Searle, Inc., nor Ortho Pharmaceutical ever has said that the decision to remove their intrauterine devices from the market was made for other than economic reasons. Both firms said they removed the devices from the market because they were faced with millions of dollars in lawsuits because of the adverse publicity about the dangers of other IUDs. There never was any question of pressure from the Church, the administration or the "extreme right wing politicians."

Yet, the authors of the editorial use the withdrawal of these devices as an excuse for accusing the Church of a complete laundry list of what they perceive as offenses. Some of these, I might point out, are in direct opposition to the positions taken by the National Conference of Catholic Bishops.

I will have to take the word of the authors that some associates and aides of Sen. Jesse Helms are Catholics, but the Church never has attempted to dictate to its members what political stands they should take. Some of the strongest opposition to Senator Helms and his positions has come from Catholic members of the Senate.

As for "hidden" Vatican financial contributions to Sen-

ator Helms, it is illegal for candidates for federal office to accept such campaign funds. If the authors of the editorial have knowledge of such unreported contributions, it is their duty to call such violations to the attention of the proper authorities. I am sure that some individual Catholics have made campaign contributions to Senator Helms, but that is their right, as American citizens.

I look forward to seeing in a future edition of the *North Carolina Medical Journal* a clarification of the position of both the journal and the North Carolina Medical Society regarding the Catholic Church.

Most Reverend John F. Donoghue
Bishop of Charlotte
P.O. Box 36776
Charlotte 28236

To the Editor:

Your permission of Dr. Crist's "editorial" labeled "Sobering Thoughts" in the November issue of the *North Carolina Medical Journal* is surprising. This editorial blasphemes Jesse Helms, our state senator, the Vatican, and the Catholic Church.

Dr. Crist's, et al, views certainly should not represent the editorial opinion of our North Carolina Medical Society as represented by the *North Carolina Medical Journal*. The article is offensive to me as a physician who happens to be a Catholic.

Is there any explanation?

Martin J. Kreshon, M.D., P.A.
Charlotte Eye Ear Nose & Throat Associates
1600 East Third Street
Charlotte 28204-3282

Response from Drs. Crist et al

The main issue we presented in our editorial, "Sobering Thoughts," is this: Should the reproductive health care policy in the state of North Carolina be determined by the Vatican or by the people of North Carolina?

On August 27, 1986, the *San Francisco Chronicle* published an article by Catholic theologian Daniel Maguire of Marquette University in which he states: "The Vatican has taken poorly to this loss of power and is struggling to regain it. Sexual and reproductive ethics is the chosen ground for that struggle. It need not have been so. The pelvic zone is not the focus of biblical morality and religion. In Galileo's time, the chosen ground was physics and astronomy, but the issue was the same: power." Papal power.

Professor Maguire further states: "(Catholic) Hierarchical lobbies affect legislation on reproductive rights and other matters. It is naive to underestimate the potential for good or ill that lies in religious bodies of that magnitude. Journalistic interest and civic concern are well warranted." We agree. We feel that the medical profession should be deeply concerned. It is this manipulation of our legislative process by the Vatican that Dr. Maguire speaks of that we find objectionable.

Our editorial presents some of the realities of the Vatican's holy war against family planning, the existence of which is beyond refute. Extraordinary documentation of

this struggle is presented in Dr. Stephen Mumford's latest book, *The Pope and the New Apocalypse*, cited in the editorial.

In their letters, Smith, Naso and Joyce say nothing of the issues or these realities. Instead, their letters offer nothing but vicious personal attacks against us and the Editor of the Journal. Webster's dictionary defines "bigot" as, "One obstinately or intolerantly devoted to his own church, party, belief or opinion." We leave it to the reader to decide which writings are bigoted.

We believe that their letters are simply crude attempts to halt discussion among North Carolina physicians of these serious issues which clearly threaten reproductive health care in this state. These letters employ the tactic of psychic terrorism directed at all readers. They seek to terrorize physicians so they dare not look critically at Catholic Church positions in American and world affairs that the Vatican prefers go unexamined and unchallenged. It remains all that, if they do, they are under the threat of being branded as anti-Catholic. We are confident that our fellow physicians will not be intimidated.

Perhaps the time has come for North Carolina physicians to collectively take a position on such Vatican interference in their delivery of reproductive health care. A survey of North Carolina physicians' attitudes toward these issues would be a reasonable next step.

Takey Crist, M.D., F.A.C.O.G., F.A.C.S.

Paul F. Williams, M.D., F.A.C.O.G.

M.R. Barnes, M.D., F.A.F.P.

H. William O'Neil, M.D., F.A.C.O.G.

Crist Clinic for Women

200 Memorial Dr.

Jacksonville 28540

Response from the Editor:

As noted on page one of each issue of the *North Carolina Medical Journal*, the North Carolina Medical Society is not considered as endorsing the opinions advanced by authors. The person or persons signing the paper are the responsible parties.

The editor considers the editorial columns open to those with convictions and strong opinions. Editorial comments do not require the factual underpinnings needed for scientific papers.

The authors of the above letters make clear that they disagree with the editorial. Most of our correspondents do not give information which allows one to balance their views against those of Crist and his co-authors.

The editorial columns of the journal are open to all who have something to say and can write interpretable English. I hope each of you with strong opinions and convictions will send material to the journal.

Eugene A. Stead, Jr., M.D.

To the Editor:

The article by Crist, Williams, Barnes and O'Neil has created significant objection by some members of the Medical Society. When one makes strong statements about politics and/or religion one may expect equal and opposite rebuttal.

Yet Crist, et al are members of the Society and as such

have a right to express themselves on controversial issues of interest to the Society at large. They have expressed themselves strongly and not with complete accuracy (since Tom Ellis is not Catholic — he told me so himself).

The Editor has recognized the issues in medical practice and chose to publish the article. To do otherwise would have constituted censorship. I agree with him.

Any apology for this article should come from the authors and obviously not from the Editor. I suggest that all readers refer to the masthead which quotes the constitution of the Society in regard to contents of the *Journal*.

Charles W. Styron, M.D.
Chairman, Editorial Board
North Carolina Medical Journal
615 St. Mary's Street
Raleigh 27605

To Dr. Styron:

Although neither you nor Dr. Stead has asked for it, here is my opinion about the letters on the Crist et al editorial. Louis Shaffner heard me on the subject over the phone and holds similar opinions; my letter is serving for both of us since I have a secretary and he does not at the moment.

Briefly, my reaction is "If the shoe fits, wear it." If Drs. Naso and Joyce find errors of fact in the editorial they should tell us. Drs. Crist and coauthors are clearly identified and the masthead says that their opinions are not necessarily those of the Society. Louis points out that this statement comes from our constitution and does not clearly include editorials, though neither of us sees why it should not. The Pope and other Roman Catholics are not shy about stating their opinions and I am sure that we will hear from those of that persuasion, and from like-thinking Protestants, on this subject. Short of another gun-related piece I can think of little which would provoke more effusion from our readership.

Robert W. Prichard, M.D.
The Bowman Gray School of Medicine
Department of Pathology
300 South Hawthorne Road
Winston-Salem 27103

To the Editor:

Drs. Crist, Williams, Barnes, and O'Neil are to be commended for their excellent editorial "Sobering Thoughts" in the November '86 issue of the *North Carolina Medical Journal*. The editorial had an important message and was correct as far as it went.

Despite the opinions of some bigoted religious institutions, rights are not absolute and total. A person's right to reproduce must be balanced against the rights of society to avoid the misery and suffering inevitably associated with severe overpopulation.

It is only by having free and open discussion of serious issues that we can maintain our democracy. It took courage for Drs. Crist et al to write the editorial and for the NCMJ to publish it.

Albert D. Warshauer, M.D.
1608 East Fifth Street
Greenville 27834

HISTORY OF CAROLINA DOCTORS CARE

As hospitals, private industry, government and insurance organizations with their control of capital have gained increasing influence over health care policy decisions, physicians have found themselves with less and less influence over their professional lives. They have become increasingly concerned with the implied threat to their freedom to discharge their responsibility to ensure quality patient care.

The NCMS Executive Committee in 1985 appointed a task force to recommend ways the NCMS could assist its members in regaining a voice in the medical decision-making process. After careful review and analysis, the task force recommended that the NCMS sponsor a statewide PPO. In May 1986 the House of Delegates overwhelmingly approved the concept. NCMS officers were charged with appointing a Board of Directors and providing startup funding.

In June 1986 Carolina Doctors Care was incorporated as a for-profit corporation and in August 1986 its first subsidiary, Carolina Doctors Care PPO (CDC), was incorporated. Committees were established in finance, recruitment, utilization management, marketing, credentialing and networking. A stock offering was initiated through Blarron Group, Inc. of Raleigh to finance the company long term.

RAISON D'ETRE

Practicing physicians everywhere must seriously address the implications of a changing health care environment. Prepaid plans are moving rapidly into North Carolina. Ultimately, each one of us will be faced with a decision to sign contracts or lose patients. Carolina Doctors Care PPO, Inc. offers us a physician-sponsored, owned and regulated alternative.

The ideal way to practice medicine in the American free enterprise system is still the time-tested fee-for-service system. Through our PPO, this system can be preserved.

A major thrust of CDC will be to unify physicians so that: (a) they are less easily exploited by reimbursers, (b) their negotiating leverage is strengthened, and (c) their professional decisions about quality care will not be superseded by business decisions.

No managed health care plan can function without physicians. As a profession, we must recognize our strength and position ourselves to influence the future of North Carolina medicine. CDC offers these opportunities.

There will always be change. Our

challenge is to manage change so that our professional standards are not submerged in a commercial scramble for profits. CDC, with your help, accepts this challenge.

LOGO

The logo, "Carolina Doctors Care," was conceived by two NCMS Auxilians. Notice that the State image is superimposed on the background word CARE, suggesting that we are a statewide organization. The word CARE serves both as a noun — the name of a corporation — and a verb — expressing a poignant message from physicians to the public: Carolina Doctors Care, and we do!

WHAT IS A PPO?

A preferred provider organization (PPO) provides quality health care at reasonable rates. It is a partnership between physicians and businesses to contain rising health care costs. Physicians agree to accept a negotiated fee for specific services and to comply with ongoing utilization review. In exchange, employers provide economic incentives to their employees to use PPO physicians.

Your PPO is not an insurance plan. Employers remain self-funded or retain their existing insurance carriers, and because current benefit plans are maintained, fee-for-service compensation is preserved.

FEE SURVEYS SENT OUT

On October 24, 1986, a confidential physician fee survey was sent out to all NCMS members. Please return the completed surveys to our consultants, Deloitte Haskins & Sells, 2100 Southern National Center, Charlotte 28202 as soon as possible. If you did not receive a confidential fee survey or if you have any questions, please call Carolina Doctors Care at 1/800/331-2877 or 919/828-1789.

PPO PRESENTATIONS

Presentations on our PPO are being given throughout the state to inform physicians about the organization and its potential and purpose. If you'd like to set one up in your area call Carolina Doctors Care.

Become a participating physician in the Carolina Doctors Care PPO. This is your organization, sponsored by your North Carolina Medical Society to assist you in fulfilling your professional responsibility by assuring physician input into health care policy decisions and the reallocation of the dollars saved by high-quality cost effective health care delivery by patients, employers and physicians.



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IN STATE

January 21

GI Update: Cancer Surveillance and the Role of Biopsy in Gastrointestinal Diseases (GI)
 Place: Greenville
 Fee: \$55
 Credit: 7 hours Category I AMA
 Info: The Office of CME, ECU School of Medicine, Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

February 11

The Psychiatric Aspects of Life Threatening Illness
 Place: Greenville
 Fee: \$30
 Credit: 3.5 hours Category I AMA
 Info: The Office of CME, ECU School of Medicine, Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

February 20

Pediatrics Day 1987
 Place: Greenville
 Fee: \$55
 Credit: 6 hours Category I AMA
 Info: The Office of CME, ECU School of Medicine, Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

March 5-12

Review of Clinical Chemistry for Practicing Pathologists & Clinical Chemists
 Place: Greenville
 Fee: \$315
 Credit: 40 hours Category I AMA
 Info: The Office of CME, ECU School of Medicine, Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

March 11

Family Practice Update '87
 Place: Greenville
 Fee: \$55
 Credit: 7 hours Category I AMA
 Info: The Office of CME, ECU School of Medicine, Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

March 21

Eighth Annual Pulmonary Disease Update
 Place: Greenville
 Fee: \$55
 Credit: 6.5 hours Category I AMA
 Info: The Office of CME, ECU School of Medicine, Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

March 26-27

Growth Control and Cancer: Molecular Approaches and Clinical Implications
 Place: Chapel Hill
 Info: Dianne Shaw, Lineberger Cancer Research Center, School of Medicine, University of North Carolina, Chapel Hill 27514. 919/966-3036

April 3

Rehabilitation Medicine: Head Injuries
 Place: Greenville
 Credit: 7 hours Category I AMA
 Info: Office of CME, ECU School of Medicine, P.O. Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

April 3-5

Sixth Annual Ultrasound Symposium
 Place: Greensboro
 Credit: 16 hours Category I AMA
 Info: Sharon Hughes, President, NC Ultrasound Society. 919/748-4505

April 9

North Carolina Clinical Neuro-Ophthalmology Review
 Place: Chapel Hill
 Info: Baird S. Grimson, M.D., Dept of Ophthalmology, University of North Carolina, 617 Clinical Science Bldg. 229H, Chapel Hill 27514. 919/966-5296

April 10

Plasma Cell Myeloma and Related Diseases
 Place: Durham
 Credit: 6 hours Category I AMA
 Fee: \$75
 Info: Myeloma Symposium, Box 3096 DUMC, Durham 27710

April 10-11

Advanced Cardiac Life Support Provider Course
 Place: Asheville
 Credit: 16 hours Category I AMA
 Fee: \$200
 Info: Daniel L. Dolan, M.D., MAHEC, 501 Biltmore Ave., Asheville 28801-4686. 704/258-0881

April 22

Neonatal Emergencies: Recognition and Treatment
 Place: Greenville
 Credit: 6 hours Category I AMA
 Fee: \$55
 Info: Office of CME, ECU School of Medicine, P.O. Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

Nursing

Except where otherwise noted, contact Nettie Wilburn, CPS, Office of Continuing Education, University of North Carolina, Chapel Hill 27514. 919/966-3638

January 13 - April 21

Comprehensive Gerontological Nursing
 Place: Greenville
 Credit: 2 Graduate; 3 CEUs
 Fee: \$3

January 16 - May 15

Child and Adolescent Nurse: Caring for the Ill Child
 Place: Chapel Hill
 Credit: 3.97 CEUs
 Fee: \$270

January 20

Rehabilitating Nursing: Integration with Therapy (AREN video conference)
 Place: Durham
 Info: Prof. Robert Bartlett, Dept of Physical Therapy, Box 3965 DUMC, Durham 27710. 919/684-2650

February 12-13

Communication Skills for the Nurse Manager
 Place: Chapel Hill
 Credit: 1.32 CEUs
 Fee: \$150

February 19-20

Human Response to AIDS — Coping and Caring
 Place: Chapel Hill
 Credit: 1.32 CEUs
 Fee: \$70

February 20-21

Writing and Publishing
Place: Chapel Hill
Credit: 2.04 CEUs
Fee: \$180

OUT OF STATE

January 19-23

Diagnostic Radiology Seminars

Place: Ixtapa, Mexico
Credit: 22 hours Category I AMA
Fee: \$495

Info: Radiology Postgraduate Education, University of California, Room C324, Third & Parnassus Ave., San Francisco, CA 94143-0628. 415/476-5731

January 26-29

Alton D. Brashear Postgraduate Course in Head & Neck Anatomy

Place: Richmond, VA
Fee: \$225-\$375
Credit: 40 hours AGD, AAGP
Info: Hugo R. Seibel, M.D., Dept. of Anatomy, Box 709, Medical College of Virginia, Richmond, VA 23298

January 29-31

Cardiology '87: Controversies in Therapy

Place: San Diego, CA
Credit: 18 hours Category I AMA
Fee: \$275, \$200 nurses
Info: Nomi Feldman, Conference Coordinator, 3770 Tansy, San Diego, CA 92121. 619/453-6222

January 30 - February 1

Sixth Annual Perspectives on New Diagnostic and Therapeutic Techniques in Clinical Cardiology

Place: Lake Buena Vista, FL
Fee: \$315 ACC members; \$380 non-members
Credit: 14.5 hours Category I AMA; AAFP
Info: Extramural Programs Dept., American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 301/897-5400, ext. 226; 800/253-INFO

February 1-6

Diagnostic Radiology Seminars

Place: Aspen, CO
Credit: 26 hours Category I AMA
Fee: \$495
Info: 415/476-5808

February 2-4

Anatomic Basis for New Cardiac Imaging Techniques

Place: Bethesda, MD
Fee: \$415 ACC members; \$465 non-members
Credit: 17.5 hours Category I AMA
Info: Heart House Learning Center, American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 301/897-5400; 800/253-INFO

February 3-8

16th Annual Pediatric Postgraduate Course

Place: Palm Springs, CA
Credit: 18 hours Category I AMA
Info: Ann J. Boehme, Schneider Children's Hospital of Long Island Jewish Medical Center, New Hyde Park, NY 11042. 718/470-8650

February 10-13

Cardiopulmonary Rehabilitation: Status '87

Place: Orlando, FL
Fee: \$275; \$175 Nurse, Therapist, Allied Health Professional
Credit: 19.5 hours Category I AMA
Info: Kathy Liebhauer, Division of CME, 1938 West University Ave., Gainesville, FL 32603. 904/392-1701

February 20-21

Flexible Fiberoptic Sigmoidoscopy

Place: Augusta, GA
Info: Division of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

February 21-28

Duke at Vail: Symposium on Inflammatory Diseases

Place: Vail, CO
Credit: 20 hours Category I AMA
Fee: \$350; \$250 Residents and Interns
Info: Angelika Langen, Box 3135 DUMC, Durham 27710. 919/684-2504

February 22-25

Rheumatology at Snowshoe

Place: Snowshoe, WV
Credit: 15 hours Category I AMA
Fee: \$225
Info: Office of CME, West Virginia University School of Medicine, G-104 Basic Sciences Bldg., Morgantown, WV 26506. 304/293-3937

February 22-27

Diagnostic Imaging: Update 1987

Place: Park City, UT
Credit: 24.5 hours Category I AMA
Fee: \$495
Info: 415/476-5808

February 23-28

6th Annual West Coast Symposium in Doppler Ultrasound

Place: Newport Beach, CA
Credit: 30 hours Category I AMA
Info: Lisa Krehbiel, Institute for Medical Studies, 30131 Town Center Dr., Ste 215, Laguna Niguel, CA 92677. 714/495-4499

February 23-28

Symposium in Doppler & 2-D Echocardiography

Place: San Antonio, TX
Fee: \$895
Credit: 40 hours Category I AMA
Info: Lisa Krehbiel, 30131 Town Center Dr. #215, Laguna Niguel, CA 92677. 714/495-4499

February 25-28

The Nineteenth Teaching Conference in Clinical Cardiology

Place: Bal Harbour, FL
Fee: \$400; \$375 Fellows & members AHA Council on Clinical Cardiology; \$250 physicians in training
Credit: 28 hours Category I AMA; AAFP
Info: Michael S. Gordon, M.D., Ph.D., University of Miami School of Medicine (D-41), P.O. Box 016960, Miami, FL 33101. 305/547-6491

February 26-28

Cardiovascular Surgery

Place: Bethesda, MD
Credit: 18 hours Category I AMA
Fee: \$415 ACC members, \$465 non-members
Info: Program Registrar, Heart House Learning Center, American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814, 301/897-5400, ext 241, or 800/253-INFO

February 27-28

Advance Trauma Life Support

Place: Mountain Home, TN
Info: Ramona Miller, Ph.D., Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

March 1-7

Update '87: Office Obstetrics and Gynecology

Place: Park City, UT
Info: Charlene E. Lee, Scott & White Memorial Hospital, 2401 South 31st St., Temple, TX 76508. 817/774-4073

March 2-7 (and April 27-May 2)

22nd Annual Family Practice Symposium

Place: Augusta, GA
Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

March 4-8

Pan American Allergy Society Annual Training Course & Seminar

Place: San Antonio, TX
Fee: \$415 members
Info: Betty Kahler, PAAS, 229 Parking Way, Lake Jackson, TX 77566. 409/297-8964 or 297-4069

March 6-7

Cardiology Department Management Conference

Place: New Orleans, LA

Credit: 10 hours Category I AMA

Fee: \$350 approx.

Info: Lisa Krehbiel, Institute for Medical Studies, 30131 Town Center Dr. Ste. 215, Laguna Niguel, CA 92677. 714/495-4499

March 7-8

Breast Imaging Update

Place: San Francisco, CA

Credit: 13 hours Category I AMA

Fee: \$295

Info: 415/476-5808

March 8-13

Annual Meeting, US-Canadian Division of the International Academy of Pathology

Place: Chicago, IL

Info: Nathan Kuafman, M.D., Secretary-Treasurer, US-Canadian Division, International Academy of Pathology, Bldg. C, Ste. B, 3515 Wheeler Rd., Augusta, GA 30909. 404/733-7550

March 9-13

Hawaii '87: Critical Issues in Primary Care

Place: Kauai, HI

Credit: 20 hours Category I AMA, AAFP

Info: The Pacific Institute of CME, P.O. Box 1059, Koloa, Kauai, HI 96756. 808/742-7471

March 9-13

Diagnostic Radiology

Place: San Francisco, CA

Credit: 34 hours Category I AMA

Fee: \$495

Info: 415/476-5808

March 14-15

Contemporary Trends in Diagnostic Nuclear Medicine

Place: San Francisco, CA

Fee: \$352

Info: 415/476-5808

March 16-20

Diagnostic Imaging 1987

Place: Kauai, HI

Credit: 24 hours Category I AMA

Fee: \$495

Info: 415/476-5808

March 29-April 1

Cardiology Update

Place: Phoenix, AZ

Credit: 26 hours Category I AMA

Fee: \$395 approx.

Info: Lisa Krehbiel, Institute for Medical Studies, 30131 Town Center Dr. Ste 215, Laguna Niguel, CA 92677. 714/495-4499

April 3-5

Ophthalmologic Plastic Surgery, Orbital Disease, and Neuro-Ophthalmology

Place: Williamsburg, VA

Fee: \$315

Info: Kay Parrott, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 9-11

Thoracic Imaging Update

Place: Monterey, CA

Credit: 13 hours Category I AMA

Fee: \$295

Info: 415/476-5808

April 10-12

OB/GYN and Abdominal Sonography: Update '87

Place: San Francisco, CA

Credit: 14.5 hours Category I AMA

Fee: \$325

Info: 415/476-5808

April 10-12

5th Annual MCV Symposium: New Trends in Anesthesia

Place: Williamsburg, VA

Fee: \$275

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 10-12

22nd Annual Pediatric Springfest

Place: Williamsburg, VA

Fee: \$250

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 23-25

23rd Annual Postgraduate Course in Radiology: The Chest

Place: Richmond, VA

Fee: \$325

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 24-26

9th Annual Conference on Emergency Medicine for the Primary Care Physician

Place: Williamsburg, VA

Fee: \$295

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 24-26

7th Annual Clinical Concerns in Primary Care: Office Cardiology

Place: Williamsburg, VA

Fee: \$295

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 27-May 2 (and March 2-7)

22nd Annual Family Practice Symposium

Place: Augusta, GA

Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

May 8-10

6th Annual MCV Cardiology Conference

Place: Williamsburg, VA

Fee: \$325

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

May 18-19

14th Annual Hans Berger Day and EEG Symposium

Place: Richmond, VA

Fee: \$250

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

May 23-25

Gynecologic Urology and Pelvic Surgery

Place: Williamsburg, VA

Fee: \$260

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

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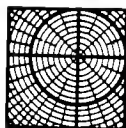
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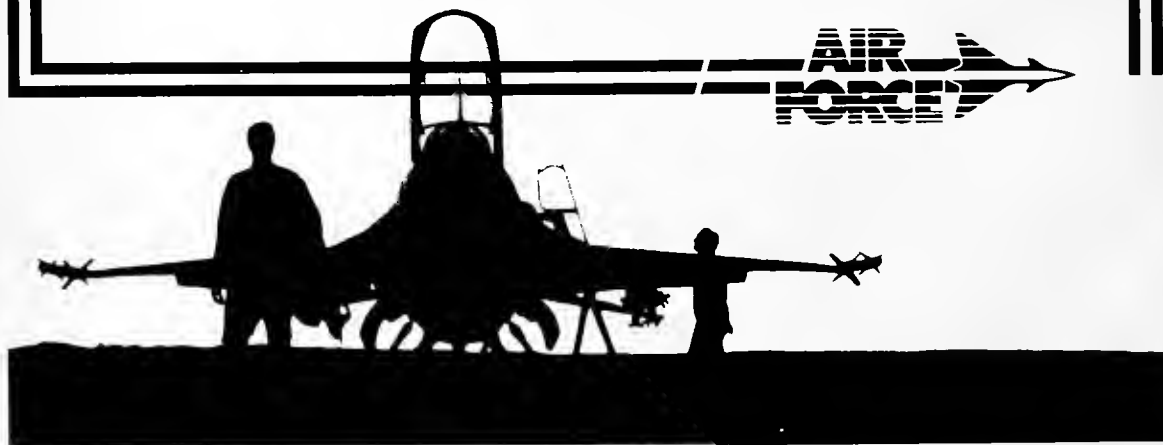


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NORTH CAROLINA: GREENSBORO, expanding emergency department/level II trauma center. Group looking for full and part-time physicians. Minimum requirement — Board eligibility in Emergency Medicine. Send CV to Norman Mayer, M.D., Post Office Box 29066, Greensboro 27408. 919/379-3965.

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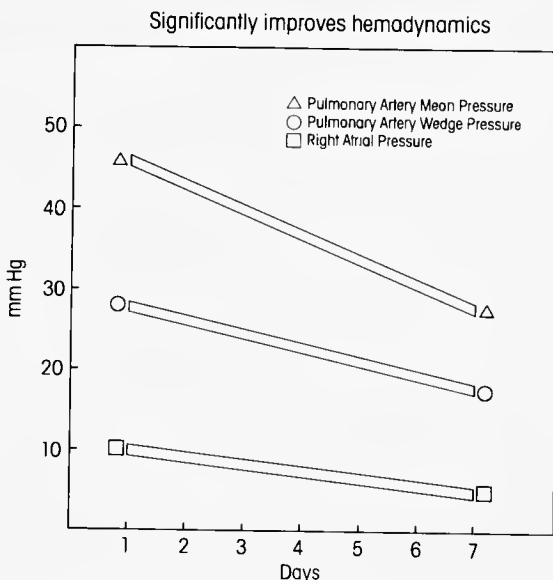
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CONTRAINDICATIONS: Anuria. Hypersensitivity and in patients in hepatic coma or in states of severe electrolyte depletion. Although Bumex can be used to induce diuresis in renal insufficiency, any marked increase in blood urea nitrogen or creatinine, or the development of oliguria during therapy of patients with progressive renal disease, is an indication for discontinuation of treatment.

WARNINGS: Dose should be adjusted to patient's needs. Excessive doses or too frequent administration can lead to profound water loss, electrolyte depletion, dehydration, reduction in blood volume and circulatory collapse with the possibility of vascular thrombosis and embolism, particularly in elderly patients.

Prevention of hypokalemia requires particular attention in patients receiving digitalis and diuretics for congestive heart failure, hepatic cirrhosis and ascites, states of aldosterone excess with normal renal function, potassium-losing nephropathy, certain diarrheal states, or other states where hypokalemia is thought to represent particular added risks to the patients. In patients with hepatic cirrhosis and ascites, sudden alterations of electrolyte balance may precipitate hepatic encephalopathy and coma. Treatment in such patients is best initiated in the hospital with small doses and careful monitoring of the patient's clinical status and electrolyte balance. Supplemental potassium and/or spironolactone may prevent hypokalemia and metabolic alkalosis in these patients.

In cats, dogs and guinea pigs, Bumex has been shown to produce ototoxicity. Since Bumex is about 40 to 60 times as potent as furosemide, it is anticipated that blood levels necessary to produce ototoxicity will rarely be achieved. The potential for ototoxicity increases with intravenous therapy, especially at high doses.

Patients allergic to sulfonamides may show hypersensitivity to Bumex.

PRECAUTIONS: Measure serum potassium periodically and add potassium supplements or potassium-sparing diuretics, if necessary. Periodic determinations of other electrolytes are advised in patients treated with high doses or for prolonged periods, particularly in those on low salt diets. Hypernatremia may occur. Reversible elevations of the BUN and creatinine may occur, especially with dehydration and in patients with renal insufficiency. Bumex may increase urinary calcium excretion.

Possibility of effect on glucose metabolism exists. Periodic determinations of blood sugar should be done, particularly in patients with diabetes or suspected latent diabetes.

Patients should be observed regularly for possible occurrence of blood dyscrasias, liver damage or idiosyncratic reactions.

Especially in presence of impaired renal function, use of parenterally administered Bumex should be avoided in patients to whom aminoglycoside antibiotics are also being given, except in life-threatening conditions.

Drugs with nephrotoxic potential and bumetanide should not be administered simultaneously. Since lithium reduces renal clearance and adds a high risk of lithium toxicity, it should not be given with diuretics.

Probenecid should not be administered concurrently with Bumex.

Concurrent therapy with indomethacin not recommended.

Bumex may potentiate the effects of antihypertensive drugs, necessitating reduction in dosage.

Interaction studies in humans have shown no effect on digoxin blood levels.

Interaction studies in humans have shown Bumex to have no effect on warfarin metabolism or on plasma prothrombin activity.

Pregnancy: Bumex should be given to a pregnant woman only if the potential benefit justifies the potential risk to the fetus.

Bumetanide may be excreted in breast milk.

Pediatric Use: Safety and effectiveness below age 18 not established.

ADVERSE REACTIONS: Muscle cramps, dizziness, hypotension, headache and nausea, and encephalopathy (in patients with preexisting liver disease).

Less frequent clinical adverse reactions are weakness, impaired hearing, rash, pruritus, hives, electrocardiogram changes, abdominal pain, arthritic pain, musculoskeletal pain and vomiting. Other clinical adverse reactions are vertigo, chest pain, ear discomfort, fatigue, dehydration, sweating, hyperventilation, dry mouth, upset stomach, renal failure, asterix, itching, nipple tenderness, diarrhea, premature ejaculation and difficulty maintaining an erection.

Laboratory abnormalities reported are hypernatremia, azotemia, hyperglycemia, increased serum creatinine, hypochloremia, hypokalemia, hyponatremia, and variations in CO_2 content, bicarbonate, phosphorus and calcium. Although manifestations of the pharmacologic action of Bumex, these conditions may become more pronounced by intensive therapy. Diuresis induced by Bumex may also rarely be accompanied by changes in LOH, total serum bilirubin, serum proteins, SGOT, SGPT, alkaline phosphatase, cholesterol, creatinine clearance, deviations in hemoglobin, prothrombin time, hematocrit, platelet counts and differential counts. Increases in urinary glucose and urinary protein have also been seen.

DOSEAGE AND ADMINISTRATION:

Oral Administration: The usual total daily dosage is 0.5 to 2.0 mg and in most patients is given as a single dose.

Parenteral Administration: Administer to patients (IV or IM) with GI absorption problem or who cannot take oral. The usual initial dose is 0.5 to 1 mg given over 1 to 2 minutes. If insufficient response, a second or third dose may be given at 2 to 3 hour intervals up to a maximum of 10 mg a day.

HOW SUPPLIED: Tablets, 0.5 mg (light green), 1 mg (yellow) and 2 mg (peach); bottles of 100 and 500, Prescription Paks of 30, Tel-E-Dose® cartons of 100. Imprint on tablets: 0.5 mg—ROCHE BUMEX 0.5, 1 mg—ROCHE BUMEX 1, 2 mg—ROCHE BUMEX 2.

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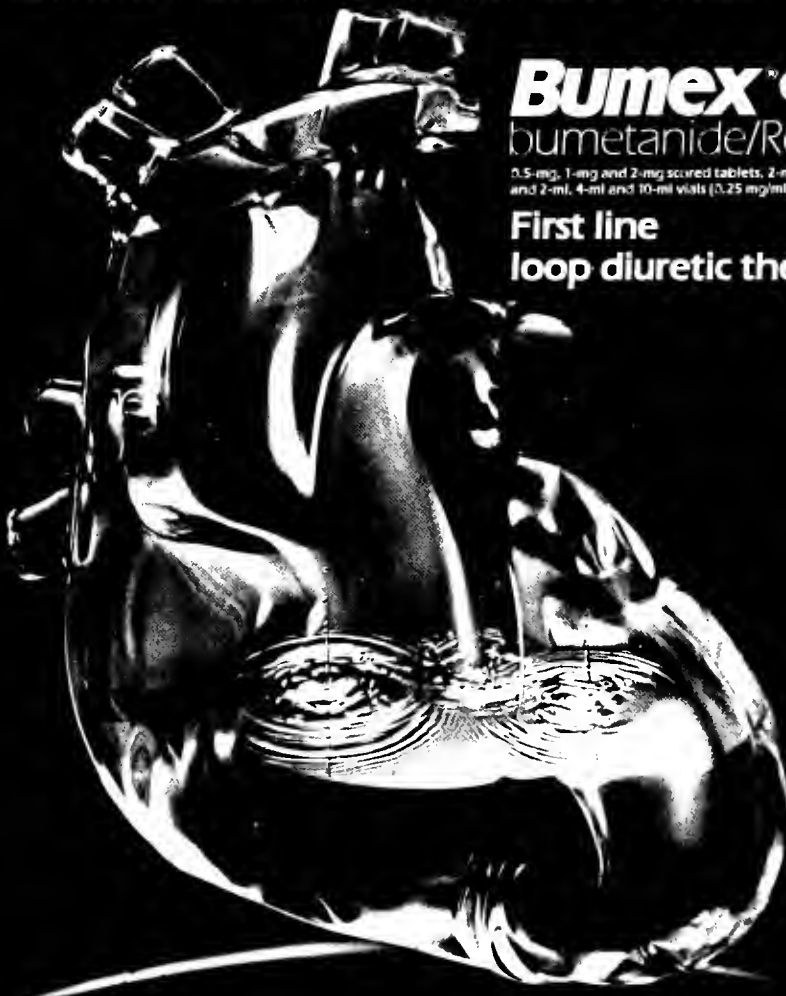
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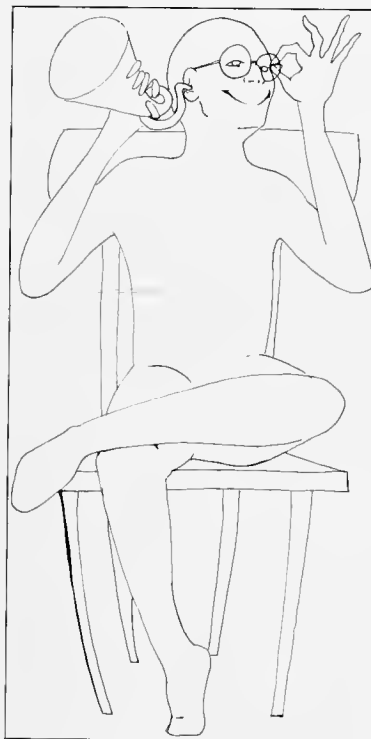
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The Official Journal of the NORTH CAROLINA MEDICAL SOCIETY

February 1987, Volume 48, Number 2

Advances for the Hearing Impaired Assistive Listening Devices

Robert D. Wolford, M.S.
page 77



Some More "Facts" About Your Eyes Looking into the Myths

Calvin H. Mitchell, M.D.
page 82

Medical Review of North Carolina — Update on Medicare

D. John Godehn, Jr., M.D. page 61

Pituitary Tumors in Eastern North Carolina

George Crawley, M.S. and William W. Fore, M.D. page 64

Are We Winning the War Against Cancer?

R. Wayne Rundles, M.D. page 69

The View from the Bed

Mark W. Swaim page 95

Table of Contents page 59

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North Carolina

MEDICAL JOURNAL

for doctors and their patients

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volume 48, no. 2, February 1987

CONTENTS

Special Article

- Medical Review of North Carolina —
Update on Medicare Review *D. John Godehn, Jr.* 61

Scientific Article

- Pituitary Tumors in Eastern North Carolina *George Crawley and William W. Fore* 64

Editorials

- Catholicism and Ethics: A Reply to the Editorial Entitled "Sobering Thoughts" *Stanley Hauerwas* 67
Are We Winning the War Against Cancer *R. Wayne Rundles* 69
Beyond the Operative Permit *James P. Weaver* 74

Learning Experiences from UNC

- Heparin Induced Hyperkalemia *Franklin W. Maddux* 75

Features for Patients

- Advances for the Hearing Impaired: Assistive Listening Devices *Robert D. Wolford* 77
Some More "Facts" About Your Eyes *Calvin H. Mitchell* 82
What Is a Hospital Chaplain? *P. Wesley Aitken* 85

Physicians' Forum

- Policing the Practice of Medicine *edited by Eugene W. Linfors* 89

Medical Education

- The View from the Bed *Mark W. Swain* 95

The Patient from Whom I Learned Most

- Remembering Bonnie *Richard D. Kenney* 96

- Official Call — House of Delegates 98

- Letters to the Editor 99

- Instructions to Authors 72

Bulletin Board

- New Members 100
Continuing Medical Education 101

- Classified Advertisements 107

- Index to Advertisers 108

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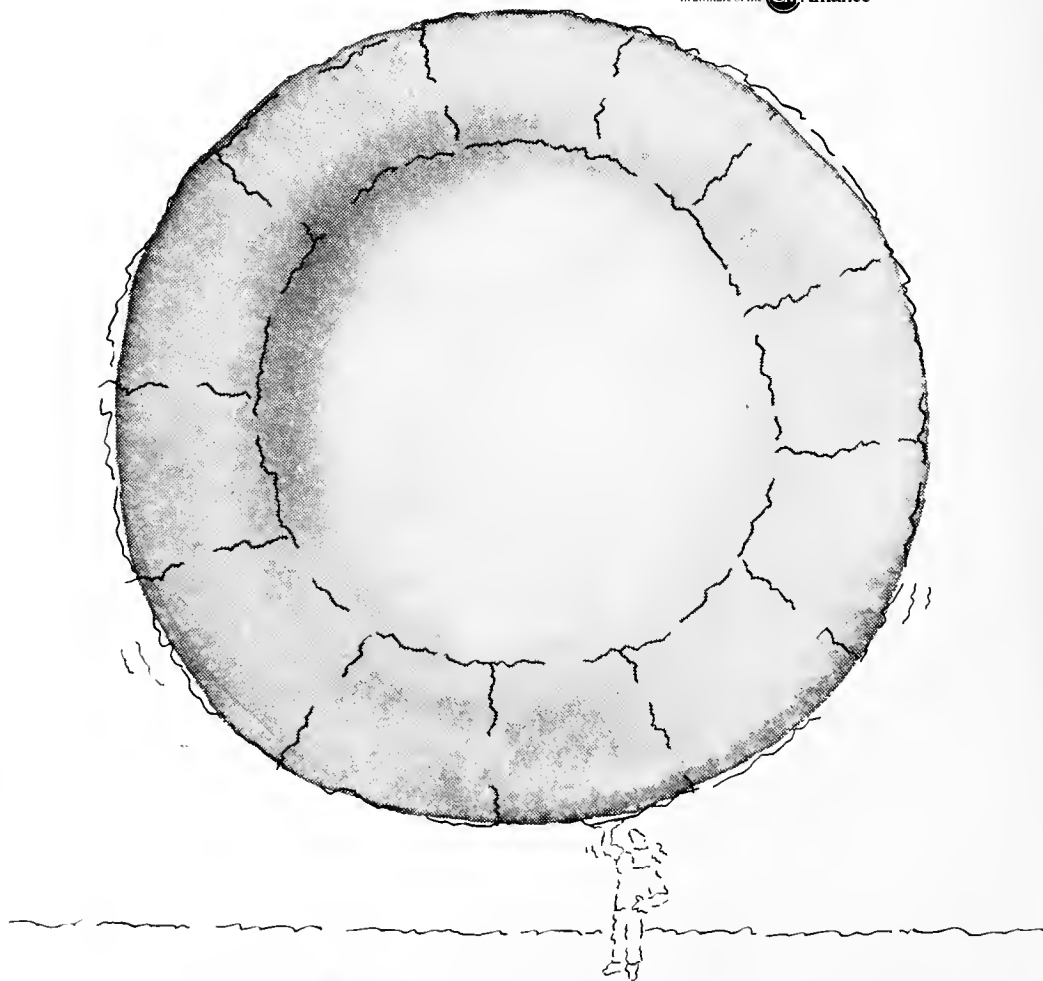
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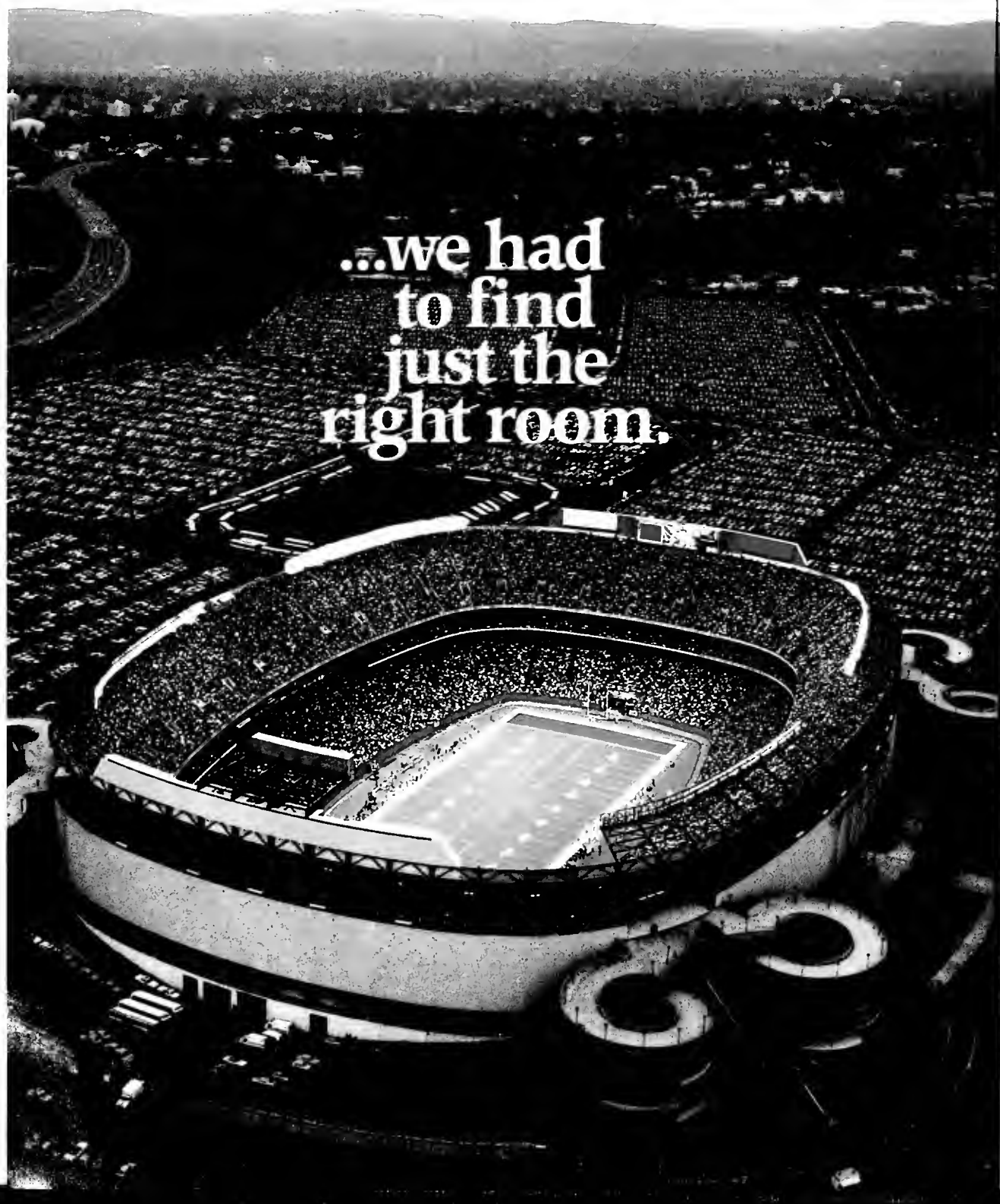
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Please see next page for brief summary of prescribing information

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BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION SEE PACKAGE CIRCULAR)

INDERAL[®] LA (brand of propranolol hydrochloride) (Long Acting Capsules)

DESCRIPTION. Inderal LA is formulated to provide a sustained release of propranolol hydrochloride. Inderal LA is available as 80 mg, 120 mg, and 160 mg capsules.

CLINICAL PHARMACOLOGY. Inderal LA is a nonselective beta-adrenergic receptor blocking agent possessing no other autonomic nervous system activity. It specifically competes with beta-adrenergic receptor stimulating agents for available receptor sites. When access to beta-receptor sites is blocked by Inderal LA, the chronotropic, inotropic, and vasodilator responses to beta-adrenergic stimulation are decreased proportionately.

Inderal LA Capsules (80, 120, and 160 mg) release propranolol HCl at a controlled and predictable rate. Peak blood levels following dosing with Inderal LA occur at about 6 hours and the apparent plasma half-life is about 10 hours. When measured at steady state over a 24-hour period the areas under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of Inderal LA tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol, resulting from the slower rate of absorption of propranolol. Over a twenty-four (24) hour period blood levels are fairly constant for about twelve (12) hours then decline exponentially.

Inderal LA should not be considered a simple mg for mg substitute for conventional propranolol and the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to Inderal LA from conventional propranolol, a possible need for reinitiation upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, Inderal LA has been therapeutically equivalent to the same mg dose of conventional Inderal LA as shown by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure and rate pressure product. Inderal LA can provide effective beta blockade for a 24-hour period.

The mechanism of the antihypertensive effect of Inderal LA has not been established. Among the factors that may be involved in contributing to the antihypertensive action are (1) decreased cardiac output, (2) inhibition of renin release by the kidneys, and (3) diminution of tonic sympathetic nerve outflow from vasomotor centers in the brain. Although total peripheral resistance may increase initially, it tends to fall below the pretreatment level with chronic use. Effects on plasma volume appear to be minor and somewhat variable. Inderal LA has been shown to cause a small increase in serum potassium concentration when used in the treatment of hypertensive patients.

In angina pectoris, propranolol generally reduces the oxygen requirement of the heart at any given level of effort by blocking the catecholamine-induced increases in the heart rate, systolic blood pressure, and the velocity and extent of myocardial contraction. Propranolol may increase oxygen requirements by increasing left ventricular fiber length and diastolic pressure and systolic ejection period. The net physiologic effect of beta-adrenergic blockade is usually advantageous and is manifested during exercise by delayed onset of pain and increased work capacity.

In dosages greater than required for beta blockade, Inderal LA also exerts a quinidine-like or anesthetic-like membrane action which affects the cardiac action potential. The significance of the membrane action in the treatment of arrhythmias is uncertain.

The mechanism of the antiarrhythmic effect of propranolol has not been established. Beta-adrenergic receptors have been demonstrated in the pial vessels of the brain.

Beta receptor blockade can be useful in conditions in which, because of pathologic or functional changes, sympathetic activity is detrimental to the patient. But there are also situations in which sympathetic stimulation is vital. For example, in patients with severely damaged hearts, adequate ventricular function is maintained by virtue of sympathetic drive which should be preserved. In the presence of AV block, greater than first degree, beta blockade may prevent the necessary facilitating effect of sympathetic activity on conduction. Beta blockade results in bronchial constriction by interfering with adrenergic bronchodilator activity which should be preserved in patients subject to bronchospasm.

Propranolol is not significantly dialyzable.

INDICATIONS AND USAGE. **Hypertension:** Inderal LA is indicated in the management of hypertension, it may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. Inderal LA is not indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: Inderal LA is indicated for the long-term management of patients with angina pectoris.

Migraine: Inderal LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: Inderal LA is useful in the management of hypertrophic subaortic stenosis, especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. Inderal LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. Inderal LA is contraindicated in 1) cardiogenic shock, 2) sinus bradycardia and greater than first degree block, 3) bronchial asthma, 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with Inderal LA.

WARNINGS. **CARDIAC FAILURE.** Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or Inderal LA should be discontinued (gradually if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of Inderal LA therapy. Therefore, when discontinuance of Inderal LA is planned, the dosage should be gradually reduced over at least a few weeks, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If Inderal LA therapy is interrupted and exacerbation of angina occurs, it is usually advisable to reinstitute Inderal LA therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema) - PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. Inderal LA should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY. The necessity or desirability of withdrawal of beta-blocking therapy prior

to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Inderal (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, e.g., dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension.

DIABETES AND HYPOLYCEMIA. Beta-adrenergic blockade may prevent the appearance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more difficult to adjust the dosage of insulin.

HYPERTOXICOSIS. Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid function tests.

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. General: Propranolol should be used with caution in patients with impaired hepatic or renal function. Inderal (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta-adrenergic receptor blockade can cause reduction of intraocular pressure. Patients should be told that Inderal LA may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

Clinical Laboratory Tests: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS. Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if Inderal LA is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncope, attacks, or orthostatic hypotension.

Carcinogenesis, Mutagenesis, Impairment of Fertility. Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

Pregnancy. Pregnancy Category C. Inderal LA has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. Inderal LA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. Inderal LA is excreted in human milk. Caution should be exercised when Inderal LA is administered to a nursing woman.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: bradycardia, congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud type.

Central Nervous System: lightheadedness, mental depression manifested by insomnia, lassitude, weakness, fatigue, reversible mental depression progressing to cataplexy, visual disturbances, hallucinations, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Gastrointestinal: nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: bronchospasm.

Hematologic: agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Dermatologic: alopecia, LE-like reactions, photosensitivity rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Ocular mucous membrane reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (praloclor) have not been associated with propranolol.

DOSEAGE AND ADMINISTRATION. Inderal LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from Inderal LA capsules to Inderal LA capsules, care should be taken to assure that the desired therapeutic effect is maintained. Inderal LA should not be considered a simple mg for mg substitute for Inderal LA. Inderal LA has different kinetics and produces lower blood levels. Retitration may be necessary especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION - Dosage must be individualized. The initial oral dosage is 80 mg Inderal LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood-pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily. In some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS - Dosage must be individualized. Starting with 80 mg Inderal LA once daily, the usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimum migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximum dose, Inderal LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTENSIVE SUBAORTIC STENOSIS - 80-160 mg Inderal LA once daily.

PEDIATRIC DOSAGE - At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

*The appearance of these capsules is a registered trademark of Ayerst Laboratories.

REFERENCES:

1. Inderal LA National Compliance Evaluation Program. Data on file, Ayerst Laboratories.
2. Ravid M, Lang R, Jullin I. The relative antihypertensive potency of propranolol, oxprenolol, atenolol, and metoprolol given once daily. *Arch Intern Med* 1985; 145:1321-1323.

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Medical Review of North Carolina — Update on Medicare Review

D. John Godehn, Jr., M.D.

ON August 1, 1986, Medical Review of North Carolina, Inc. (MRNC) began its second two-year contract for Peer Review Organization (PRO) Medicare review. Although MRNC must perform review under stringent guidelines from the Health Care Financing Administration, and although MRNC's budget was reduced by almost \$1 million from its previous contract, the organization continues to feel that keeping control and responsibility for review in the hands of the state's physicians is in everyone's best interest.

MRNC believes that broad physician involvement is critical to the success of true peer review. Currently over 2,500 North Carolina physicians are members of MRNC, and over 500 physicians in active practice serve as reviewers. While medical records are screened initially by nonphysician reviewers using established criteria, all review decisions are made by physicians.

All physician reviewers of a case must concur for an adverse decision to be final. Although reviewers attend instructional sessions and are expected to follow MRNC-developed guidelines, such as the directive that close calls be made in favor of the attending physician, reviewers are nonetheless expected to use independent judgment in making their decisions.

Reviewer discretion sometimes can cause inconsistencies in review decisions, and decisions with which the attending may disagree, but such freedom is felt most compatible with true peer review and helps avoid the creation of rigid standards of care. Reviewer performance is monitored by MRNC. MRNC also must periodically send samples of reviewed cases to Super PRO, an organization in California, for evaluation of the quality of its reviews.

Emphasis on Quality of Care Review

During the initial PRO contract period, the Health Care Financing Administration (HCFA) placed major emphasis on utilization review. Review for quality of care tended to be incidental. Because of concern from many quarters that the Prospective Payment/Diagnosis Related Grouping (DRG) system could engender premature discharging and other decreases in quality care, Congress has mandated that quality review be a prime activity in the present PRO contracts. Moreover, it stipulated that severe penalties be imposed against physicians or hospitals found to have provided poor quality care. Therefore, in addition to review

for appropriateness of admission and DRG validation, each case reviewed by the MRNC for any reason now will be subjected to review for quality of care using HCFA-mandated generic screens.

The HCFA quality screens will provide for the monitoring of such areas as medical stability of the patient at the time of discharge, hospital deaths, nosocomial infections, and unscheduled return to the operating room. All readmissions within 15 days will be reviewed to determine if necessary care was provided during the first admission and if the patient was medically stable at the time of discharge. Other quality-of-care issues include inappropriate patient management which results or may result in patient harm, and failure of the medical record to document provision of appropriate care. Copies of all of these screens have been provided to each hospital by MRNC and should be available to their medical staffs.

If application of the generic screens identifies a case as a potential quality problem, it will be referred to a physician reviewer. If this reviewer feels a quality problem may exist, the attending physician will be notified and asked to provide clarifying information. The medical record and this additional information are then reviewed by a second physician. At least one of the physician reviewers must be of the same specialty as the attending physician. If both physician reviewers concur that a quality problem exists, the attending physician will be notified of the finding and of the potential seriousness of the situation. As part of the review procedure, each reviewer will assign a quality Severity Level Index (SLI) to the case, ranging from one (no quality problem) to five (significant patient harm or significant potential for such harm). Generally, for quality problems of moderate severity (SLI three or four), action will be taken against the physician only when a pattern of poor quality emerges. For serious problems (SLI five), the case will be referred immediately to the three-physician Quality Review Panel at MRNC. The panel reviews the case, and may recommend initiation of sanction proceedings against the physician.

There are certain situations in which federal guidelines mandate specific punitive measures against a physician or hospital. The so-called "prohibited actions," which a physician or hospital must be particularly careful to avoid, include discharge before the patient is medically stable resulting in readmission to the same hospital. If such an action occurs, payment for the second admission is denied and the provider may be placed on intensified review. If

three episodes occur within a three-month period, sanctions must be instituted against the physician or hospital. Moreover, if the prohibited action results or could result in serious patient harm or death (a so-called "gross and flagrant violation"), then sanctions *must* be initiated against the provider based on that single case.

Thus, keys for physician survival under the scrutiny of peer review would seem to be: admit only when necessary; provide good-quality care; discharge or transfer only when the patient is clearly ready; and clearly document the care given and its rationale, particularly when best judgment dictates care that deviates from established criteria or norms.

Short Stay and Ambulatory Surgery Admissions

MRNC has noted some confusion regarding the appropriateness of admissions for short stays and for normally ambulatory surgical, diagnostic or therapeutic procedures. Its review policy, based on federal guidelines, is that if hospital-level care of 24 hours or less is necessary, then the patient should not be admitted under the Prospective Payment System (DRG payment). Rather the patient should

be handled as an ambulatory case or short-stay admission and billed under Medicare Part B.

Generally, patients should not be admitted for procedures on MRNC's Ambulatory Surgery List, unless during the post-procedure observation period a complication arises requiring inpatient care. Predisposing medical or social factors for increased surgical risk do not automatically justify admission for such procedures unless during the postoperative period a need for prolonged hospital care of greater than 24 hours becomes apparent and is documented. Likewise, if a patient is seen in the Emergency Department or clinic and the need for admission is not completely clear, a potentially inappropriate admission — one that could be denied on review — should be avoided, and the patient should be managed or observed on an outpatient status for up to 24 hours while the need for admission clarifies itself.

This policy does not require that the hospital establish a separate observation unit. The patient could be managed using normal hospital facilities, but handled administratively as an ambulatory patient for billing purposes during the short stay or observation period. □

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Pituitary Tumors in Eastern North Carolina

George Crawley, M.S., and William W. Fore, M.D.

• *A review of the pituitary surgical experience of Eastern Carolina Neurosurgical Associates, Inc.*

PITUITARY tumors are not uncommon. One unselected autopsy study found pituitary tumors in 27% of those studied.¹ Even though not all of these tumors cause problems, many patients do become symptomatic and many times the cause of their symptoms is not recognized until the tumors are large and/or the endocrine abnormalities are far advanced. Small pituitary tumors can be treated medically or by a less disfiguring and safer transsphenoidal approach. Early diagnosis and transsphenoidal surgery are frequently associated with normal postoperative endocrine function, especially if the neurosurgeon can leave a portion of normal pituitary tissue in place.

The technique of transsphenoidal surgery for pituitary resection has been an available therapeutic option at Pitt County Memorial Hospital (PCMH) since 1976. Since that time, 48 patients from eastern North Carolina have had surgery for pituitary adenomas. Recent interest in the medical treatment of pituitary adenoma and questions about the efficacy of surgery in producing long-term cure led us to review our experience with pituitary surgery at PCMH. We have suspected for some time that our patients have more advanced tumors than those reported in other hospitals.²⁻⁵ Our study compares our experience to that of others.

Methods

Data were obtained by chart review of all patients who have undergone pituitary surgery at PCMH since 1976. All the surgery was performed by Eastern Carolina Neurosurgical Associates (ECNA). We identified 48 patients representing 49 operations over the last 10 years. There were 27 women and 21 men in our series and 42% were black. The average age of the patients was 48 years, with a range from 14 to 82 years. Patients who had not been seen in the past two years were asked their health status including any currently used medications. We sent out 22 letters and received 17 responses; five patients were not available for accurate follow-up.

Results

Using their preoperative endocrine evaluations, we could classify our patients as hyperfunctional (prolactinoma, acromegaly, Cushing's), normal endocrine function, or hy-

pofunctional. Forty percent of the tumors were hyperfunctional, 30% were hypofunctional, and 26% had no detected endocrine abnormality. Most patients in the hypofunctional category showed clinical signs of panhypopituitarism that were mentioned in their chart records, although in some cases this was not documented by preoperative laboratory work, especially the earlier cases from 1976 to 1980 when prolactin, human growth hormone (HGH), and adrenocorticotrophic hormone (ACTH) assays were not as readily available.

Our patients presented most often with visual difficulty (47%) and headache (33%) (table 1). Vision problems

Table 1
Pituitary Tumor Patients — Presenting Symptoms and Signs

	% of Pts. with Symptoms*
Visual Symptoms	46%
Headache	33%
Amenorrhea and/or Galactorrhea	19%
Weakness	19%
Gynecomastia and/or Impotence	6%
Diabetes Mellitus and Hypertension	6%
Acral Enlargement	4%
Other (Sinusitis, Dyspnea, Incidental Sellar Enlargement)	6%

*Patients often had more than one symptom.

included temporal hemianopsia, "deteriorating" vision, diplopia, and visual field cuts. The combination of visual difficulty with a functioning pituitary tumor was uncommon; only two of our patients who presented with visual symptoms had evidence of excess hormonal secretion. The other patients with visual field problems had normal or hypofunctional endocrine status.

Hyperprolactinemia was the most common endocrine abnormality. Twenty-four percent of our patients showed symptoms of secondary amenorrhea/galactorrhea in women and gynecomastia and/or impotence in men. Problems due to hyperadrenalism and growth hormone excess were less common, with only three patients with Cushing's syndrome and four acromegalic patients identified.

Of the 49 operations, 37 (74%) were performed by the transsphenoidal route and 12 (26%) by transfrontal cran-

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iotomy. Transsphenoidal surgery was the procedure of choice unless a contraindication existed. The indications for transsphenoidal surgery are: (1) tumors confined to the sella turcica; (2) tumors associated with cerebrospinal rhinorrhea or pituitary apoplexy; (3) tumors with sphenoid sinus extension; (4) patients with paracentral scotoma; (5) pituitary adenomas with suprasellar extension confined to midline.

Transfrontal craniotomy was associated with a higher morbidity and longer hospital stay averaging 16.2 days, while transsphenoidal patients averaged only 8.8 days in the hospital. Of the twelve patients with transfrontal surgery, six had complications. Two patients have permanent diabetes insipidus from impairment of antidiuretic hormone secretion, and one of these patients also had cerebrospinal fluid rhinorrhea (CSF leak) which was treated conservatively. Two patients suffered bone flap necrosis. One patient had oculomotor nerve damage and another had olfactory nerve damage.

The one death listed in our transsphenoidal series (table 2) was from pulmonary embolus six days postoperatively. One patient hemorrhaged from the right cavernous sinus and subsequently lost an estimated 3,000 ml of blood before hemostasis was achieved. A case of meningitis occurred in the same patient who suffered permanent diabetes insipidus, and this patient also exhibited CSF leak.

We identified five women with preoperative prolactin ≤ 200 ng/ml. Postoperatively, two women achieved normal prolactin levels and two remained hyperprolactinemic. One woman has not had a postoperative prolactin determination. Clinically, the two women with normal prolactin values and the one without postoperative prolactin determination have resumed irregular menses and their galactorrhea has resolved. One woman, who remains hyperprolactinemic, has resumed menses but still has galactorrhea. The other hyperprolactinemic patient continues to have amenorrhea/galactorrhea. Patients who have microadenomas and a preoperative prolactin level ≤ 200 ng/ml have the highest surgical cure ratio.^{6,7}

Six men and four women were identified with preoperative prolactin in excess of 200 ng/ml. Only one man has a normal postoperative PRL from this group. The four women have remained amenorrheic, but galactorrhea has resolved in three of them. A preoperative prolactin level of ≤ 200 ng/ml is associated with an increased cure ratio, compared to patients with a preoperative level of >200 ng/ml.^{6,8}

Acromegaly was identified in four patients. Three of these patients now have normal HGH levels, while the fourth has a moderately elevated HGH level (12.4 ng/ml).

Cushing's disease was found in three patients. Two are in remission, while the third retains an elevated ACTH level and has recently undergone Bragg peak proton-beam irradiation to the sella.

Seventeen of our 23 patients who presented with visual deficits have improved vision, while six noted no improvement. None of these patients suffered further loss of vision after surgery. This indicates that the earlier one realizes that a pituitary tumor is responsible for visual loss, the better the prognosis.

Discussion

We found some significant differences between our cases and other published series: (1) patients with pituitary tumors in eastern North Carolina have larger tumors than most such patients; and (2) our percentage of patients presenting with visual deficits is more than double that of other series.^{2,3} Patients with visual deficits are those whose tumors compress or involve the optic apparatus by extrasellar extension. We feel this symptom to be caused by a delay in diagnosis. Is the delay due to characteristics of our patient population?

We looked at socioeconomic reasons to explain this increased incidence of large tumors. Our patients are from a predominantly rural area, although 83% came from the larger towns in eastern North Carolina with better access to physicians than many eastern counties.

Only 61% of the patients or their spouses were employed; only 43% had health insurance coverage. Our patients reflected the racial mix of eastern North Carolina. As a group, our patients are different socioeconomically from most of the reported series from metropolitan areas and do represent a group that will visit physicians less often than insured neighbors.

What are the problems associated with late diagnosis? One of the major problems is that the surgeon must operate on very large tumors by transfrontal craniotomy instead of the safer and less disfiguring transsphenoidal surgery. The percentage of transfrontal craniotomies performed at PCMH is 10 times higher than that at Wilson in San Francisco.²

The second major problem is loss of vision. Earlier reviews of the ocular manifestations of pituitary disease found a higher incidence of visual problems than present in our series.⁹⁻¹¹ Visual problems occurred in 47% and are comparable with the patient series collected by Wray between 1974 and 1975 (44%),¹² but much higher than a consecutive review of patients in Montreal, Canada between 1976 and 1981 (12%).¹³ Anderson strongly makes the point that the role of the ophthalmologist in this disease is changing. He recommends that an ophthalmologist be willing to question patients about reproduction and sexual dysfunction, examine the patients before turning off the room lights for eye examination, and perform visual fields in the evaluation of patients with headache.¹⁴

Our patients with hypopituitarism give special cause for concern. Since the clinical symptoms and signs point to the patient's problem, the tumor causing the hypopitui-

Table 2
Transsphenoidal Complications

	ENA %	#	2, 3, 4, 5 Other Series
Death	2.7	(1)	0.4 - 2.7%
Meningitis	2.7	(1)	0.49- 2.0%
Hemorrhage	2.7	(1)	0.49- 4.0%
CSF Leak	8.1	(3)	1.47- 6.4%
Permanent diabetes insipidus	2.7	(1)	2.4- 5.6%
Transient diabetes insipidus	21.6	(8)	3.6-28.0%
#Patients		37	825

Table 3
Symptoms of Hypopituitarism

Deficiency	Clinical Manifestation
HGH	Fasting hypoglycemia
LH, FSH	Loss of sexual hair; oligomenorrhea; amenorrhea; ↓ libido; loss of firmness or testicular size. ↓ in facial hair
TSH	Hypothyroidism with normal or low TSH
ACTH	Loss of axillary hair in females; hypotension; history of difficult recovery from surgical stress
β-lipotropin (βLPH)	Decreased pigmentation

tarism might be discovered early enough that permanent visual deficit or a disfiguring transfrontal craniotomy could be avoided.

We believe that area physicians and ophthalmologists should consider pituitary tumors earlier in their differential diagnosis when seeing patients who present with some symptoms of hypopituitarism (table 3). Alertness to symptoms of hypopituitarism helps, but half of our patients with tumors large enough to compress the optic nerve had no endocrine deficit.

Continued compression of normal pituicytes by tumor will lead to secondary hypothyroidism. This condition has many of the same clinical features as primary hypothyroidism (cold intolerance, dry scaly skin and hair, lethargy, constipation, etc.), but there are a few clues that suggest secondary hypothyroidism. In women, a history of amenorrhea instead of menorrhagia is suggestive of hypothyroidism due to a tumor because of earlier loss of gonadotropins. Most importantly, patients with symptoms and signs of hypothyroidism have low or normal serum thyroid-stimulating hormone (TSH) levels. A serum TSH assay is mandatory to confirm that a pituitary tumor is not the cause of the hypothyroid state. These clues should alert the clinician to the possibility of a pituitary tumor.

Patients who have lost ACTH function generally have tumors large enough to produce other symptoms such as headache, visual field deficits, and deficiency of other anterior pituitary hormones. Nevertheless, one patient presented with acute adrenal insufficiency. Weakness, fatigue, and orthostatic hypotension are early symptoms, albeit vague ones. Morning values of serum cortisol ≤ 10 $\mu\text{g/dl}$ or low 24-hour urine free cortisol tests are suggestive of adrenal insufficiency. Determining the cause of the adrenal failure can be difficult, but a rise in serum cortisol in response to exogenous ACTH administration occurs in

pituitary disease. An acceptable stimulation test procedure is found on the package insert of the synthetic ACTH available in most hospital pharmacies.

Conclusion

There are numerous factors that have caused this patient group to have larger tumors and more visual problems. However, we want this review of our experience to alert physicians elsewhere to consider pituitary tumors as the source of symptoms in patients with headache, visual problems, loss of libido, and menstrual problems before the tumor has caused irreparable damage to the optic nerves or destroyed all functional pituitary tissue. □

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Catholicism and Ethics: A Reply to the Editorial Entitled "Sobering Thoughts"

Stanley Hauerwas, Ph.D., Professor of Theological Ethics

I have been asked to respond to the editorial, "Sobering Thoughts" (Crist et al, NCMJ 1986; 47:511), as well as the correspondence which that editorial elicited. It was thought that some more "objective" response might be useful. I have some acquaintance with medical protocols and, therefore, before responding to the substantive issues raised by the editorial, I should establish my credentials for providing a more "objective" reaction. I currently teach theology and ethics at the Divinity School at Duke University. I have taught at the University of Texas Medical Branch at Galveston as well as lectured at other medical schools and medical conventions. I have done work in the philosophy and history of medicine as well as medical ethics. I have recently published a book, *Suffering Presence* (University of Notre Dame, 1986), which deals with medicine from a theological perspective. Though I am a Protestant I taught in the Department of Theology at the University of Notre Dame for fourteen years. Though my time at Notre Dame may seem to qualify my ability to be objective, I think it helped me appreciate what an extraordinarily diverse and rich tradition and community Catholicism represents.

I must say, however, I find the editorial blatantly anti-Catholic. I suspect such anti-Catholicism derives more from ignorance than from clear anti-Catholic prejudice. North Carolina has fewer Catholics than any state in the Union. Those of us raised as Southerners often have little experience and/or knowledge of individual Catholics and even less of the Catholic Church as an institution. As a result, it is easier to attribute power and attitudes to Catholics that in fact are not the case exactly because we do not know them.

I can say that the view of Catholicism in the editorial is simply blatantly false. The Catholic Church is certainly no monolith in which the Vatican sets policy that becomes marching orders for bishops, much less individual Catholics. I saw many times activities and events sponsored at Notre Dame anger the local bishop, but he knew well that he should not, and he did not, intervene. That is not to say that the Catholic Church does not have clear moral statements about contraception and abortion. Yet even the official church is not of one mind about how those moral positions should be translated into law and/or policies for all societies. Indeed, part of the internal debate in the American Catholic Church concerning abortion is over the difficult issue of knowing how best to translate Catholic

moral attitudes into societal expression in a society like ours. That is why many Catholics favor having an adequate family allowance for all people in our country rather than, or alongside, restrictive laws against abortion.

A more important issue raised by the editorial, however, has nothing to do with Catholicism per se. For the more important issue is whether any religiously committed people are prohibited from expressing their moral convictions politically if those convictions are correlative to their religious beliefs. These are extremely complex matters, both socially and legally in our society, but at least we should be clear about some things. Most importantly, it should be acknowledged that there is nothing in the Constitution that prohibits religious people and/or groups from trying to influence our government. Our Constitution does not, as is often alleged, erect a wall of separation between church and state. That is not a phrase in the Constitution. Neither the disestablishment clause nor the freedom of religion clause prohibits religious bodies per se from political involvement. How the disestablishment of religion in our Constitution is always to be harmonized with the freedom of religion is not easily resolved. What should be clear, however, is that religious convictions do not disqualify one from being an active citizen.

For example, I certainly hope that Catholics will continue to support the sanctuary movement in the southwestern part of the United States. Moreover, I think the Catholic Church has shown extraordinary sensitivity to the problem of how we are to treat justly the illegal immigrants who have been used in this country to provide cheap labor. In no way do I wish to prejudge how as a society we should finally resolve these issues, but at the very least I would not want the Catholic witness in these respects to be disqualified because they are Catholic.

The other set of important issues raised by the editorial that bear much more discussion are, of course, those dealing with birth control or, as the editorial puts it, with "the patient's right to reproductive freedom." I should like to point out that the latter phrase is question-begging as it is by no means clear that our society in fact believes in an unexceptional right of reproductive freedom. Sterilization is still on the books in many states. Would the authors of "Sobering Thoughts" support the "right of reproductive freedom" for mentally handicapped people who want to have children? Again I do not wish to prejudge this issue, though as one long associated with agencies committed to the care of the mentally handicapped, I think the issue is

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by no means as straightforward as many think. Rather all I wish to indicate is that phrases such as "right to reproductive freedom" often cover over issues that require much fuller examination.

In fact no policy, law, or people in our society prevent women from securing birth control if they want it. As far as I know there is no organized attempt on the part of Roman Catholics or anyone else in our society to try to outlaw the sale of condoms and/or the pill. I certainly know of no organized campaign of Roman Catholics against the IUD. There has been a discussion among Catholic moral theologians concerning whether the IUD ought to be understood as a contraceptive or abortive device but, as far as I know, that issue has not been resolved.

There are, however, very troubling issues involved in questions of whether the government should positively encourage women to use birth control. This is true even if such encouragement involves only providing birth control information and/or devices. This is particularly the case if, as the authors of the editorial obliquely suggest, such information is or should be aimed at population control. For as has often been pointed out in the literature

concerning the ethics of such policy, what is sometimes done in the name of population control is in fact an attempt to target certain populations unjustly. That is why many in the black community protest against those who seem so concerned to "help" blacks secure abortions. In a racist society such as ours, a governmental program targeted at helping poor women have abortions can appear as threatening genocide. Whites tend to react to such a suggestion in unbelief, but if we had suffered from racism we might well view the matter quite differently.

I am in no way suggesting that governments should be prohibited from having a proper concern with population growth. Rather I am only suggesting that a much finer grain of moral analysis is required than that provided by the authors of "Sobering Thoughts." I have to confess that Senator Helms is a long way from my favorite senator, but we will make little headway on understanding these issues morally if we begin with political name-calling and/or fanciful political intrigue. If an editorial like "Sobering Thoughts" is an occasion for us to begin to think soberly about these issues then perhaps some good will have been done. □

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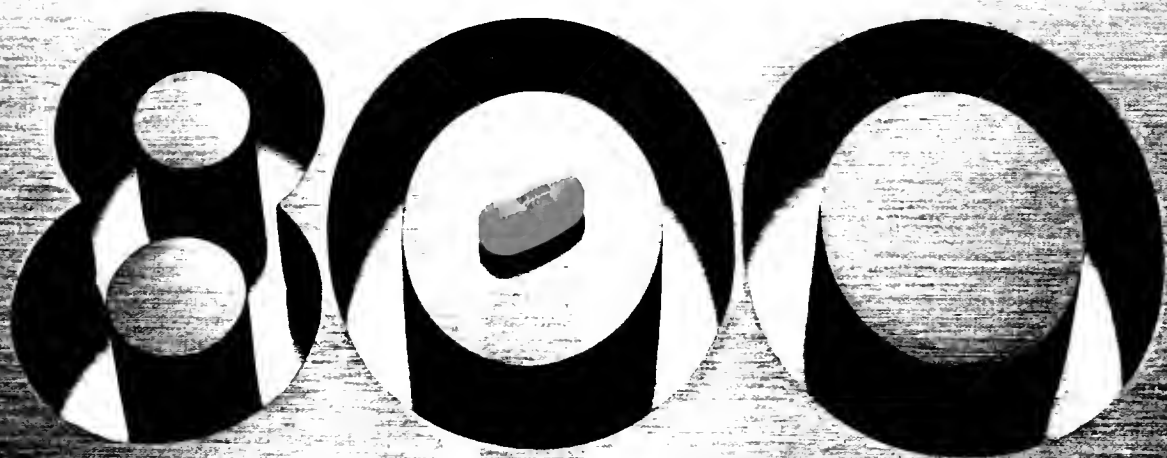
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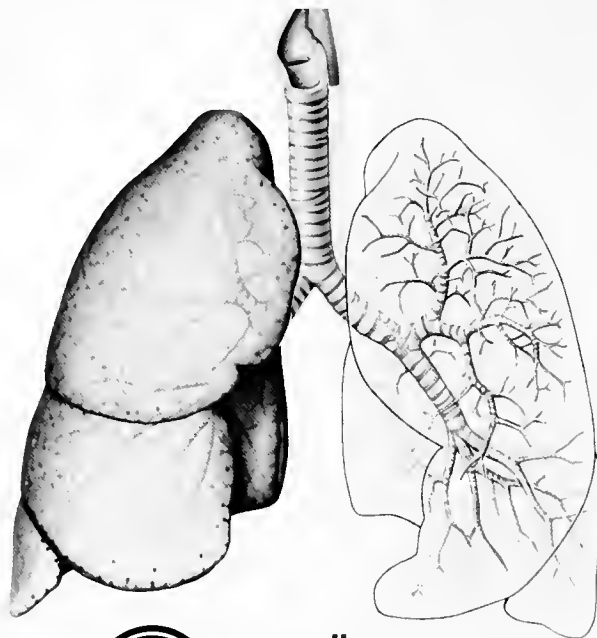


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- Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor

penetrates mother's milk. Exercise caution in prescribing for these patients.

Adverse Reactions: (percentage of patients)

- Therapy-related adverse reactions are uncommon. Those reported include:
 - Gastrointestinal (mostly diarrhea) 2.5%
 - Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment.
 - Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, erythema multiforme, serum-sickness-like reactions): 1.5%, usually subside within a few days after cessation of therapy. These reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.
- Other: eosinophilia, 2%; genital pruritus or vaginitis, less than 1%.

Abnormalities in laboratory results of uncertain etiology

- Slight elevations in hepatic enzymes.
- Transient fluctuations in leukocyte count (especially in infants and children).
- Abnormal urinalysis; elevations in BUN or serum creatinine.
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Are We Winning the War Against Cancer?

R. Wayne Rundles, M.D.

IN May 1986, John Bailar and Elaine Smith of the Department of Biostatistics, Harvard School of Public Health, published a report in the *New England Journal of Medicine* posing the general question, "Are we winning the war against cancer?"¹ Using one statistical yardstick — the age-adjusted mortality rate, which adjusts for changes in age distribution as well as in population size — and combining all cancer-related deaths together, they found that the overall mortality from cancer during the years 1950 to 1982 had increased by 8.5%. This increase in mortality had occurred during a period of particularly intense research and investigative effort. While admittedly there had been noteworthy improvements in the control of the less common types of cancer, better palliation, and some extension of life in those under 65, the war against cancer in their opinion was only a qualified success. They suggested that the amount of progress in cancer control had been overstated and that research emphasis should be shifted from the treatment of cancer to its prevention.

The Bailar-Smith analysis and recommendation was not what the National Cancer Institute, the American Cancer Society, and many private investigators and practitioners wanted to hear. Interested parties were quick to make rebuttals and in a recent issue of the *New England Journal of Medicine* 12 letters to the editor dissected the unsettling finding and interpretations in detail. This debate promises to continue, since it appears that "where you stand depends on where you sit."

The war against cancer was more or less officially declared when Richard Nixon signed the National Cancer Act in late 1971. This act abruptly increased funds allocated to the National Cancer Institute for the support of basic and clinical research, created a network of comprehensive cancer centers about the country and initiated "outreach control" programs. An expansion of Institute programs had been advocated for more than 10 years by the medical lobby (a group of politically oriented medical and scientific leaders), the American Cancer Society, Institute officials and others interested in cancer.

A controversial budget bypass mechanism was arranged to avoid budgetary excisions and tedious negotiations with other worthy claimants and branches of the National Institutes of Health. Recommendations for supporting the National Cancer Institute were to be presented directly to the President by a three-member advisory panel. This special budgetary treatment, and misgivings that the Institute

expansion represented a premature and lopsided emphasis on one group of categorical diseases, ruffled the feelings of a number of influential scientists, commentators and administrators. They tended to be critical of many of the programs carried out during the following 15 years, particularly the large-scale screening of chemicals and biologic agents for anti-tumor activity, the development of large clinical cooperative groups to evaluate different agents and treatment regimens, and cancer control efforts that involved public relations and public education activities.

Criticism from the scientific community was dampened considerably, though, when science advisors and study group members at the Institute continued to take a broad view of the cancer problem and gave substantial support to basic research in relevant fields of biochemistry, pharmacology, microbiology, immunology, cell biology, epidemiology, molecular biology, etc. Over the years many important diagnostic and therapeutic advances were made which to a greater or lesser extent represented dividends from cancer research: Lymphangiography, computed tomographic scans, linear accelerators for radiotherapy, agents to monitor immunologic reactions in individuals undergoing organ transplantation, control of hyperuricemia and gout, and developments in the field of molecular biology such as "oncogenes," epithelial, T-cell and platelet-derived growth factors, and a remarkable assortment of monoclonal antibodies now employed as essential reagents in AIDS and other research areas.

The Bailar-Smith Analysis: Lung Cancer and Other Factors

Virtually all commentators on the Bailar-Smith analysis of the 1950 to 1982 cancer mortality statistics regard their view of progress as being unduly pessimistic. Using only the age-adjusted death rate and combining all types of cancer together obscures many important findings. The major failure in the cancer program, as everyone recognizes, concerns cancer of the lung. During the past 35 years the mortality from this self-induced, preventable disease has increased 250%. In the U.S., mortality has begun to fall in men, but it continues to increase in women. If lung cancer were excluded from the calculations, the overall age-adjusted 1950 to 1982 mortality from cancer would not be an increase of 8.5% but a decrease of 13%. It is evident that economic and political forces have prevented any real war from being waged against lung cancer and allowed only a half-hearted skirmish.

Screening programs in the U.S. have detected lung cancer at an earlier stage, which may lead to some improvement in survival after surgery. Small cell tumors respond

From the Department of Medicine, Duke University School of Medicine, Durham 27710. This editorial appears also in *Oncology Times*, 1987; 9(Jan. 1):2, 10.

temporarily to aggressive chemotherapy but overall mortality in any case has not been reduced. There is no reason to think that statistics have been influenced by diagnostic errors or changes in pathologic criteria. Cancer is increasing most rapidly worldwide in developing countries where there has been a dramatic increase in the consumption of tobacco products. The use of tobacco increases the incidence of many types of cancer in addition to those of the lung, particularly those that originate in the mouth, throat, esophagus, bladder, kidney or pancreas. In Shanghai County, China, cancer was the sixth leading cause of death in 1960. Twenty years later it had become number one.

The incidence of cancer of the stomach during the last 50 years has fallen by 65-70%. This is generally attributed to improvements in food preservation and in dietary habits. The mortality and five-year survival rates for carcinoma of the breast in women have been relatively stable, and statistics have not yet been influenced by notable improvements in early diagnosis, the development of more acceptable surgical procedures, effective radiotherapy, improved hormone therapy and chemotherapy. The mortality from cervical cancer has declined dramatically in countries where there are well organized cytologic screening systems and well trained practitioners.

The mortality from colorectal carcinoma has declined slowly over the course of several years, due mostly to the earlier detection and better management of rectal tumors. Carcinomas of the colon grow slowly but are still not recognized as a rule until they have produced gross bleeding from the GI tract or obstruction. Earlier diagnosis and more effective treatment would be promoted by giving closer attention to individuals at higher risk, those over the age of 45 with a positive family history of polyps, colorectal carcinoma, recurrent gastrointestinal disturbances or positive tests for occult blood in the stool.

In the 1970s investigators in the fields of comparative pathology and epidemiology popularized the idea that 80-90% of cancers were caused by environmental factors, which might be identified and dealt with by large-scale "test and ban" procedures. This idea has fallen into disrepute. The environment they defined turned out to be both endogenous and exogenous, too inclusive and poorly defined to provide a basis for definitive investigation. Air pollution, chemical wastes in dump sites and ground water, occupational exposures, etc., were alleged to be etiologically important in from 3% to 75% of cancers. As better information accrued, the lower numbers seemed to be more reasonable. Some chemicals, such as vinyl chloride and monomers used in the plastic industry and benzol used in manufacturing rubber goods, have been engineered out of the workers' environment. Others, such as the potent carcinogen aflatoxin, which contaminates corn products and peanuts on occasion, are more difficult or impossible to eliminate and for practical purposes can only be controlled to an arbitrary "tolerance."

Speculations regarding the relationships of dietary and nutritional habits to cancer, beyond recognizing the importance of specific deficiencies, are necessarily based on soft data. Guidelines for a prudent diet can be recommended, however, since they have definite merit in the prevention of cardiovascular and other diseases and entail

no risk. "Chemopreventive" agents for cancer are still in a "star wars" stage of development.

Looking Ahead

Bailar and Smith have performed a useful service in calling attention to the fact that much of the cancer problem has not been solved, and that signs of progress have been disappointing to some. The National Cancer Institute's goal of reducing cancer mortality by 50% by the year 2000 is a laudable hope but one that is not supported by statistical trends. In most forms of cancer there is a long latency period, and achieving the stated goal by the year 2000 would require an almost instant reduction in cigarette smoking, a compliant public and the development of exceptional professional expertise. There is no realistic reason to think that all of these will materialize by request.

The recommendation that cancer control emphasis be shifted in a major way to cancer prevention ignores the substantial support already being given to this field. A major impediment to planning additional cancer prevention activities, furthermore, is that there are simply no rational, scientific leads at this time as to how to prevent brain tumors, leukemia, lymphoma, myeloma, hepatoma, melanoma, sarcomas, kidney tumors, endocrine tumors, or carcinoma of the pancreas, ovary or prostate.

There is increasing agreement that the traditional warning signs of cancer should be modernized to emphasize constellations of habits, signs and symptoms that in an individual of a given age, sex and genetic background may be particularly significant (see table 1). In this format item 1, for instance, relates to the well-known respiratory tract hazard of cigarette smoke, and item 2 to the local effects of tobacco on oral tissues. Item 3 summarizes the signs, symptoms and circumstances that should arouse suspicion of breast tumor in women. In item 5 the symptoms and demographic data outlined relate to a crucial matter, the early diagnosis of colorectal carcinoma. Item 6 refers to bladder and prostate carcinoma in men past middle-age and item 7 to carcinoma of the cervix which investigators

Table 1
Warning Signs of Increased Cancer Risk

1. Habit of smoking cigarettes or breathing cigarette smoke.
2. Habit of chewing tobacco, dipping snuff or heavy use of both alcohol and tobacco.
3. Palpable lump in breast after end of menstrual period, bleeding from the nipple, breast discomfort in women over 40, especially in those with a family history of breast carcinoma.
4. Frequent sunburn; change in size, color or pigmentation or bleeding from any skin lesion.
5. Recurrent abdominal pain, cramps, diarrhea, change in bowel habits or blood in stools in men or women over 45, especially in those with a family history of polyps in the colon or colorectal cancer.
6. Increasing difficulty in urination or blood in urine in men over 50.
7. Promiscuous sexual activity in young women.
8. Obesity in women, vaginal bleeding after menopause.
9. Enlarged lymph nodes, or swelling of tonsil, testis, etc.
10. Chronic cough or hoarseness.

are showing is related to papilloma viruses transmitted by sexual contact.

Winning the war against cancer will require not only sustained and sophisticated research and a high level of medical competency, but education of the public, reinforced by persuasion and example, which it is to be hoped

will lead to the adoption of optimal health habits by individuals who expect to have long and healthy lives. □

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Usage in Pregnancy: Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Precautions: In the elderly and debilitated, and in children over six, limit to smallest effective dosage (initially 10 mg or less per day) to preclude ataxia or oversedation, increasing gradually as needed and tolerated. Not recommended in children under six. Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider individual pharmacologic effects, particularly in use of potentiating drugs such as MAO inhibitors and phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions (e.g., excitement, stimulation and acute rage) have been reported in psychiatric patients and hyperactive aggressive children. Employ usual precautions in treatment of anxiety states with evidence of impending depression; suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation have been reported very rarely in patients receiving the drug and oral anticoagulants; causal relationship has not been established clinically. Due to isolated reports of exacerbation, use with caution in patients with porphyria.

Adverse Reactions: Drowsiness, ataxia and confusion may occur, especially in the elderly and debilitated. These are reversible in most instances by proper dosage adjustment, but are also occasionally observed at the lower dosage ranges. In a few instances syncope has been reported. Also encountered are isolated instances of skin eruptions, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased libido—all infrequent and generally controlled with dosage reduction, changes in EEG patterns (low-voltage fast activity) may appear during and after treatment, blood dyscrasias (including agranulocytosis), jaundice and hepatic dysfunction have been reported occasionally, making periodic blood counts and liver function tests advisable during protracted therapy.

Usual Daily Dosage: Individualize for maximum beneficial effects. **Oral—Adults:** Mild and moderate anxiety disorders and symptoms, 5 or 10 mg *t.i.d.* or *q.i.d.*, severe states, 20 or 25 mg *t.i.d.* or *q.i.d.* **Geriatric patients:** 5 mg *b.i.d.* to *q.i.d.* (See Precautions.)

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Beyond the Operative Permit

James P. Weaver, M.D.

FEW physicians would deny that Medicine is currently undergoing significant change. Each of us can easily find examples to illustrate the effects of many forces in our daily practices. Where these forces will lead us is certainly open to controversy. One point that continues to remain clear, however, is the continued primacy of the physician-patient relationship. We know that strengthening this invaluable bond will surely give us our firmest anchor in the stormy waters that seem to lay ahead.

At the November meeting of the executive committee of The North Carolina Medical Society a resolution was passed which is testimony to the Society's recognition of this fact. The resolution calls for acceptance by the Society of the concept of the "Operative Request," and calls on the Society to encourage the North Carolina chapter of the American Hospital Association, and the North Carolina chapter of the American College of Surgeons, to adopt the "Operative Request" as opposed to the "Operative Permit." We may easily see how this relates to the strength of the physician-patient relationship by briefly examining the implications and origin of the current terminology.

The words we use to describe a thing influence our concept of that thing. Examples of this would be "house" versus "home" or "acquaintance" versus "friend." Government propaganda frequently uses this technique to make unpleasanties seem more appealing, such as "Federal Deposit Insurance Corporation" instead of "tax." Simply changing a word can open up a new horizon in our conceptual awareness of an event or thing.

During surgery, the only formal statement and documentation of the physician-patient relationship is the "Operative Permit" or "Operative Consent." This piece of paper almost reaches ceremonial proportions as the physician steps forward with the familiar, "Now you must sign this so I can operate on you." The point is that under current circumstances, physicians are obtaining "permission" to operate on their patients. We have no choice, for that is the label which the law has placed on the interaction every time we have our patients sign an "Operative Permit." In essence we are obtaining "permission" to commit a battery, for the law demands that we obtain "permission" to touch another person, and this form is documentation that we have obtained that "permission."

The problem with obtaining an "Operative Permit" or "Operative Consent" is that this terminology grew out of the law; it reflects the adversarial relationship between parties in a legal encounter, and not the relationship of shared decision-making which is more appropriate in a medical encounter. Physicians have allowed the administrators and the lawyers to create forms that have labeled

the physician-patient relationship with a terminology destructive to that relationship.

As a physician, it is my duty to evaluate a patient's problem and recommend treatment. The law has made it quite clear that I should discuss the possible risks, benefits, alternative choices, and complications of my recommendation, and with these ideas I agree. The patient does not, however, give me "permission" to assault him, which is the terminology we are all using under the current system. From a physician's perspective, and indeed, from a patient's perspective, it is more appropriate that the patient either "request" our services or refuse them. He or she can do this by signing an "Operative Request."

The Veterans Administration hospitals have used an "Operative Request" since 1975, and in personal communication with the office of the General Counsel of the VA, I have been told that they have had no legal difficulty with the "request" form, and regard it as "a consent and then some" rather than something less than a consent." The "Operative Request" fills the law.

The "Operative Permit" or "Operative Consent" can be changed to an "Operative Request" by simply removing the word "Permit" or "Consent" everywhere it appears in the current form that your hospital recommends and replacing it with "Request." This single word change immediately changes the flavor of the physician-patient interaction for the better. It stops physicians from obtaining "permission" to assault their patients. "Request" is a term that is more constructive than destructive in the physician-patient relationship. It frees the relationship from the connotation of antagonism inherent in the legal jargon and consequently sets it in a more harmonious environment. It elevates the patient to a higher level in the relationship by stressing cooperative effort and not passive permission-giving by the patient. It more appropriately describes the patient as the active seeker of help, rather than the physician as the seeker of another procedure. Finally, it may strengthen the physician's legal position, for now the physician is not simply getting "permission" to operate, but complying with the patient's "request" that something be done.

By their endorsement of the "Operative Request," the North Carolina Medical Society has begun again to strengthen the essence of our medical system, the physician-patient relationship. There is hope that in the future, and with the added influence of the American Hospital Association and the American College of Surgeons, we can move beyond the "Operative Permit" and the physicians in North Carolina will no longer get "permission" to operate on their patients but rather a "request" for surgery. □

From Durham Clinic, P.A., 1830 Hillandale Road, Durham 27705.

Heparin Induced Hyperkalemia

Franklin W. Maddux, M.D.

LISTENING to the housestaff discuss a patient recently, I was reminded of a particularly valuable Pearl proffered by a faculty member several years ago.

Medical Pearls Day is an annual event in which the graduating medical school class asks selected faculty members to leave them with a parting piece of medical wisdom. A hepatologist came to mind. He was and is an engaging faculty member who is perennially asked to give a snippet of his medical knowledge. His point this day was simply that while evaluating liver function abnormalities, it is essential that the diagnostician "THINK DRUGS" while considering etiologies for the liver function abnormalities. I have found the pearl to be exceedingly pertinent and worthy of much *broader utility* than simply in the evaluation of hepatitis.

The case in point is that of a middle-aged patient admitted to the hospital with a deep venous thrombosis in the right thigh. His anticoagulation was proceeding unremarkably with intravenous heparin. He had no prior medical history of note and was on no medications at initial presentation. He was an occasional alcohol user and a two-pack-a-day smoker.

The difficulty in his management began six days after entry when routine electrolytes revealed persistent elevations in his serum potassium level. For two or three days the level was regularly between 5.8 and 6.6 mmoles/L, while work-up was without evidence of exogenous potassium intake, type IV renal tubular acidosis, tissue destruction, or infection. Resolution of the hyperkalemia was impressive when oral anticoagulation was instituted. Within 36 hours of discontinuing intravenous heparin, the patient's serum potassium was at its baseline entry value of 4.2 mmoles/L.

"Think Drugs"

As the potassium level was returning to normal, the housestaff reconsidered the predicament and uncovered the relationship between heparin and hyperkalemia.

Drug-induced hyperkalemia may be divided into three categories. The drug may be responsible for increased potassium uptake, decreased potassium excretion, or a shift from the intracellular stockpile of potassium to the extracellular compartment. Heparin and related mucopolysaccharides were noted in the early 1960s to induce natriuresis. Further, they acted to inhibit the excretion of potassium in some patients. Wilson and Goetz noted that one such patient was found to have an extremely atrophic

zona glomerulosa when the adrenal glands were pathologically examined.¹ Subsequently it has been well documented that heparin inhibits the production of aldosterone by the adrenal gland.² The adrenal suppression is selective, as glucocorticoid synthesis is unimpaired. The inhibition of aldosterone production occurs within two to five days and lasts for two to seven days following the cessation of drug therapy. Low dose and high dose regimens of heparin induce the abnormal response. Adrenal suppression is seen regardless of the route of administration.³ The effect is independent of the glucocorticoid and mineralocorticoid stimulating action of adrenocorticotrophic hormone.⁴ It appears to interfere with the angiotensin stimulation of the zona glomerulosa by inhibiting the production of the aldosterone precursor corticosterone. The effect is rapidly reversible when the drug is removed.²

Hyperkalemia from heparin induced hypoaldosteronism is a rare clinical occurrence. It has been proposed that patients with mildly compromised renal function and diabetes are at the highest risk for developing the clinical manifestation of the hypoaldosteronism state. Finally, since the causes for hyperkalemia are many, there is a gross under-recognition of the syndrome despite the potentially fatal complications.

Heparin use in the United States has increased dramatically in the past ten years. Treatment of venous thrombosis and pulmonary embolism utilize full dose intravenous heparin. Prospective studies have clearly documented the benefit of prophylactic low dose heparin to prevent thromboembolic disease in hospitalized medical and surgical patients. Further, heparin solutions are used to keep many types of peripheral and central intravenous catheters patent. The drug is used to prepare vascular graft material and to keep the hemodialysis machine functioning. Controversy exists over the efficacy of long-term subcutaneous heparin versus oral anticoagulation. Other uses are spread throughout the medical community. At North Carolina Memorial Hospital, the pharmacy reports annual usage in 1986 of 465,682,500 units.

Heparin is one of the most utilized agents in the practice of medicine. Rare complications will inevitably be realized when the use of the drug is this frequent. Therefore, the wise physician will heed Dr. Henry Lesesne's medical pearl and "think drugs" when unexplained complications arise.

□

Acknowledgment

My thanks to Ms. Gladys Battle for tallying the Heparin use at North Carolina Memorial Hospital.

From the Division of Nephrology, the University of North Carolina School of Medicine, Chapel Hill 27514.

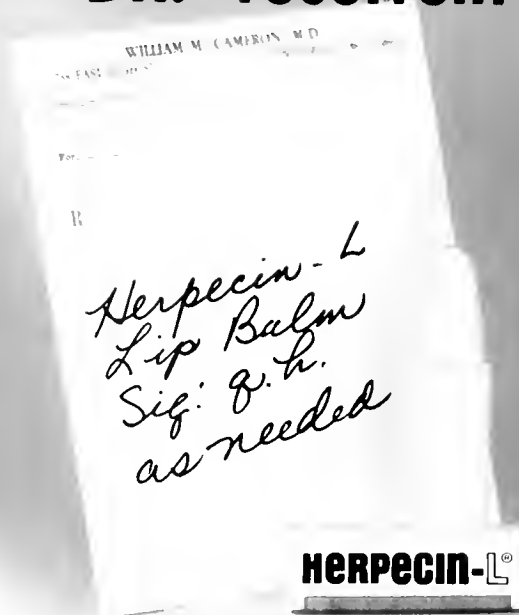
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WARNINGS

- Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1,243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
- Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
- Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
- Acute Hepatic Injury.** In rare instances, significant elevations in enzymes such as alkaline phosphatase, CPK, LDH, SGOT, SGPT, and other symptoms consistent with acute hepatic injury have been noted. These reactions have been reversible upon discontinuation of drug therapy. The relationship to CARDIZEM is uncertain in most cases, but probable in some. (See PRECAUTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic

function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS.)

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in *in vitro* bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy, Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. Diltiazem is excreted in human milk. One report suggests that concentrations in breast milk may approximate serum levels. If use of CARDIZEM is deemed essential, an alternative method of infant feeding should be instituted.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably asso-

ciated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences as well as their frequency of presentation are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%). In addition, the following events were reported infrequently (less than 1%):

Cardiovascular	Angina, arrhythmia, AV block (first degree), AV block (second or third degree) — see conduction warning, bradycardia, congestive heart failure, flushing, hypotension, palpitations, syncope
Nervous System	Annesia, gait abnormality, hallucinations, insomnia, nervousness, paresthesia, personality change, somnolence, tremor, tremor
Gastrointestinal	Anorexia, constipation, diarrhea, dyspepsia, dyspepsia, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH (see hepatic warnings), vomiting, weight increase
Dermatologic	Felchiae, pruritus, photosensitivity, urticaria
Other	Amblyopia, dyspnea, epistaxis, eye irritation, hyperglycemia, nasal congestion, nocturia, osteoarthritis, pain, polyuria, sexual difficulties

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: alopecia, gingival hyperplasia, erythema multiforme, and leukopenia. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

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North Carolina Medical Journal

Features for Patients

February 1987

Advances for the Hearing Impaired: Assistive Listening Devices

Robert D. Wolford, M.S.

It is estimated that there are between sixteen and eighteen million hearing impaired Americans, making hearing loss the most prevalent serious disability in the United States today.^{1,2} Given that approximately only four million people own hearing aids, there remain vast numbers of people who tolerate their hearing loss without benefit of any assistance.

Many of these people believe that their loss is not very severe or that a hearing aid is inappropriate for their particular type of hearing problem. There are those who experience listening problems despite the use of hearing aids who suppose that there is nothing more that can be done for them. There are also individuals who have tried hearing aids and received no benefit due to the severity of their hearing loss.

While for many people a hearing

aid will go a long way toward solving a hearing problem, it has limitations, especially in noisy environments. This is because the microphone of the hearing aid picks up all of the incoming sound and amplifies it according to the frequency output of the hearing aid. What is sacrificed in this situation is the signal-to-noise ratio. That is, the loudness of the signal (message we are trying to hear) is equal to or softer than the background noise.

Many people who are helped partially or not at all by their hearing aids are unaware of what have come to be known as Assistive Listening Devices/Systems (ALDS). ALDS is the name given to a broad range of products that are designed to solve one or more specific listening problems which hearing aids either cannot solve or can only partially alleviate. These devices are designed either to improve the signal-to-noise ratio by increasing the loudness of the signal or by transmitting the signal directly to the ear of the listener, or to sub-

stitute an alternative stimulus when amplification of the sound is not enough.

Telephone Devices/Systems

Considering that almost 10% of the population has hearing impairment, and the need for good telephone communications is a prime requisite in today's fast-paced world, it is easy to understand why telephone devices are currently the most utilized form of assistive listening device. In choosing an ALD for the telephone one must consider the individual's degree of hearing impairment as well as his or her use of the phone away from the home or office. While some people may be helped by simply selecting a phone with a clean, clear sound, others may need additional amplification from a built-in or add-on device. Still others, with severe/profound hearing loss or poor word discrimination ability, should consider a telecommunication device for the deaf.

Amplifying devices for the telephone fall into three major cate-

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gories: built-in, portable and modular. The prices of telephone amplifying devices range from \$15 to \$90.

Built-in amplifiers, usually available from the telephone company, consist of an amplifying handset with a switch and/or control that can be activated when the hearing impaired person uses the telephone.

Portable units are small disc-shaped amplifiers that slip over the earpiece of the telephone. They are held in place by an elastic band and use a small battery for power. Some of these units have a built-in telecoil capable of generating a magnetic field, inductively feeding sound to a telecoil ("T" switch) equipped hearing aid^{3,4} (figure 1).

Modular amplifiers connect directly to a modular telephone at a point between the handset cord and the housing for the dialing pad.

A **telecommunication device for the deaf** (TDD) provides the severely hearing impaired with the ability to call directly another person who has similar equipment without the need for an interpreter. This is possible because the conversation is typed through one machine and decoded by the second machine, providing a visual readout (figure 2).

All TDDs have three basic components: a keyboard for typing messages, a cradle for the handset of the telephone to permit transmission of the message, and an LED display pro-

viding the visual readout. TDDs range in price from approximately \$160 to \$1000 depending on the features selected.

Some additional features one may wish to consider are paper print-out, built-in memory allowing you to hit one key for frequently used words, and automatic answering. Ultratec, Inc., manufactures a TDD called the Superphone which can be made with an optional electronic voice and a touch-tone signal decoder. This would permit telephone conversation with anyone having a touch-tone phone. The Superphone is capable of receiving and transmitting both Bandat and ASCII codes; in effect, the Superphone can be used as a computer terminal. For deaf/blind individuals a TDD can be selected that is compatible with a Braille type printer.



Figure 1.
Two different portable telephone amplifiers



Figure 2.
A telecommunications device for the deaf

Personal Amplifying Systems

Personal amplifying systems can be divided into two major categories: systems that can be used independently from one's hearing aid and those in which the individual's hearing aid acts as part of the system. To understand amplifying systems more clearly some definitions are in order.

Hardwire devices require that the user be directly connected or "wired" to the sound source. An example of this is the use of headphones with a TV or stereo.

Induction loops use a wire that is placed around the perimeter of a room or worn around the neck. A special amplifier is attached to this wire and a magnetic field is created inside the loop. A person whose hearing aid has a "T" switch can pick up this signal as long as he or she remains inside the loop.

FM, as the name implies, is a radio system by which the transmitter, placed near the sound source, sends radio waves to a receiver worn by the listener.

Infrared is much like an FM system, but instead of radio waves the medium used is invisible light.⁵

These various systems can be used

Figure 3.
An example of an induction loop, an FM system and an infrared system



Figure 4.
Two personal amplifiers



alone or in combination, depending on the specific needs of the individual (figure 3).

People who do not have hearing aids can use hardwire systems such as the personal amplifier available from Radio Shock or the Williams Sound Pocket Talker. The Pocket Talker has a microphone jack that permits use of an extension cord so the microphone can be placed next to the TV while the listener reclines in a favorite chair (figure 4).

The physician with hearing impairment would find the amplifying stethoscope a valuable "hardwire" device. Infrared devices, which can only be used indoors, have stethoscope-type receivers with volume control adjusters and meet the needs of the mild and moderately hearing impaired. In the classroom, FM systems can be useful auditory trainers. The teacher wears a microphone-transmitter around the neck and his or her voice is picked up by the student wearing the receiver.

People who already have hearing aids can adopt these devices provided their aids have either direct audio input or an induction coil ("T" switch). Hearing aids that have direct audio input have a port into which various cords can be hardwired. These cords can be attached to a microphone, auditory trainer, tape recorder, etc. The telecoil of the hearing aid can be activated by placing a

silhouette next to the aid which is hardwired to a pickup mike or attached to one of the above devices.

The induction loop, FM, and infrared systems can be readily expanded to provide multiperson listening systems. All that is necessary is that multiple receivers be worn by the members of the group. If these multiperson systems are to be used in adjacent rooms, care must be taken when using induction loops. These loops are capable of bleed-over which could cause a listener to experience interference from the next room. FM systems have 32 different channels available to avoid this problem. Infrared systems are incapable of proper functioning if the light pathway is obstructed.

Alerting/Signaling Devices

Imagine for a moment not being able to hear your alarm clock in the morning, the ring of the telephone, or the cry of your baby in the next room. For the more than two million deaf people in the United States, this is a way of life.¹ They must learn to rely on their sense of touch or vision in order to meet the demands of day-to-day living. A variety of alerting/signaling devices have been developed which when triggered cause a light to flash or an oscillator to vibrate, thus alerting the deaf person that it is time to wake up or that there is someone at the door. These devices

can be purchased as individual units, each designed to alert the deaf person to one particular sound, or as systems that will flash a predetermined code identifying the particular sound source.

Wake-up alarms include standard and digital clocks or timers. The Flashalarm Moonbeam (Westclox, a Division of General Time Corporation, Norcross, Georgia) has a built-in strobe light that flashes at a preset time. For deaf/blind people or heavy sleepers there are alarm clocks that awaken by vibration, such as the Electro Alarm Clock Kit #2332 (American Communication Corporation, East Hartford, Connecticut) which has a vibrator attachment that can be placed under the pillow (figure 5, next page).

For the do-it-yourselfer, an inexpensive timer with a built-in electrical outlet permitting the use of a fan, light or vibrator may be all that is necessary. For those who wish to use a lamp, a flasher button that makes one lamp flash 65 to 85 times a minute can be purchased for a few dollars from a local electronics shop.

Telephone and doorbell signifiers can be in-line or separate units with a microphone that is placed next to the phone or door chime.

There are multipurpose systems that are sensitive to as many as six different sounds. These systems have transmitters that send a signal to a

receiver located in the room of the hearing impaired person. Some of these receivers are capable of transmitting FM signals to a wristwatch-like device permitting the user to move freely from room to room.

Emergency signalers flash lights, and more sophisticated devices automatically call the fire company when a smoke detector is activated.

Hearing Dogs

An alternative to assistive devices for the deaf is the hearing dog. The hearing dog program began in 1976 when the American Humane Association in Denver, Colorado began training dogs to react to specific "sounds." In 1981 the American Humane authorities selected Red Acre Farm in Staw, Massachusetts to develop a regional hearing dog center. Since that time the Red Acre Farm program has expanded and now serves most of the United States.

In keeping with the philosophy of Red Acre Farm, which is to "initiate and encourage projects that will help prevent suffering in humans and animals," the dogs are selected from various animal shelters. After a veterinary examination, the dogs undergo a four-month training program. During this period they receive obedience training and are taught to respond to certain sounds such as alarm clocks, smoke detectors, a door knock, a child's cry, or the telephone. Upon hearing a specific sound, a dog will respond by making physical contact with the owner and leading him or her to the sound source. To date there are three hearing dogs in use in North Carolina.

Closed Captioning

Telecaption decoders translate the audio portion of selected television programs into captions that are displayed on the television screen. The captions appear as white letters on a black background usually at the bottom of the screen. Decoders come cable-ready and are similar in size to most video cassette recorders. Pres-

ently there are over 90 hours per week of captioned programming on network television and up to 134 hours per week on cable television.

Through technology developed by the National Captioning Institute, closed captioning is available not just for prerecorded programs but for "live" ones as well, such as "ABC World News Tonight," "Monday Night Football," presidential speeches and other special programs. To determine if one's favorite program is closed captioned, one should look for the phrase "Closed Captioned" following the individual program listings in a program guide such as TV Guide.

Figure 5.
Phone signaler connected to a lamp



Figure 6.
A two-channel vibrotactile device with wristbands



Vibrotactile Aids

Vibrotactile aids are designed to transform airborne sound waves into vibratory patterns providing the profoundly hearing impaired with the ability to "feel" sound. The electronics case, about the size of a pack of cigarettes, picks up the incoming sound waves and sends a signal to a vibrator or vibrators worn on the wrist or chest (figure 6).

Because the skin cannot detect frequencies much in excess of 600Hz, tactile aids include special processing that lowers the frequency of higher pitched sounds such as doorbells, or

speech sounds such as "s" or "f," so that they can be felt.^{6,7}

For the wearer, tactile aids remove the isolation associated with deafness. With training, some people are able to differentiate environmental sounds and some speech sounds. Researchers have reported that in using a prototype tactile vocoder with up to 23 channels, some patients have achieved speech discrimination scores of 78% using a closed set of 100 words with no visual cues (lip reading).⁷ While this 23-channel device is not yet available to the general public, continued development of tactile aids should provide a promising alternative for those profoundly impaired people who do not receive benefit from hearing aids.

Summary

While it is appropriate for the hearing impaired to seek assistance beginning with an audiologic/otologic examination, it is no longer appropriate to think of a hearing aid as the only non-surgical/medical treatment for hearing loss. Over the past few decades, remarkable innovation has resulted in the development of a wide variety of systems for the hearing impaired.

Additional information about assistive listening devices is available from the author.

□

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TWELVE IMPECCABLE EXCUSES FOR NOT GIVING BLOOD.

1. I think I have lumbago.
2. I'm type Z negative.
3. I'm on the grapefruit diet.
4. I gave six months ago.
5. I just got back from Monaco.
6. The lines are thirteen blocks long.
7. My mother won't let me.
8. I didn't sign up.
9. I'm going out of town.
10. Asthma runs in my family.
11. I forgot to eat this morning.
12. I'm allergic to flowering magnolia.



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Some More "Facts" About Your Eyes

Calvin H. Mitchell, M.D.

In October 1983, Dr. Bruce Shields shared some eye "facts" in this journal — some common misconceptions about eye health.¹ Here are some myths that are commonly espoused by patients who come to the Duke Eye Center for an eye examination. Read through the list and see how many myths are familiar to you.

- 1 Putting off wearing glasses for reading as long as one can will allow one to continue reading to a more advanced age.
- 2 Wearing glasses makes one's eyes weak so that one has more difficulty reading without them.
- 3 Holding reading material too close will be harmful to the eyes.
- 4 Sitting too close to a television set will harm the eyes.
- 5 Reading with one eye closed or with just one eye will cause damage.
- 6 If one has glasses, he or she should wear them all the time.
- 7 Everyone over 50 years of age should have bifocal glasses.
- 8 Eye exercises will improve the eyesight so that glasses are no longer needed.
- 9 Looking at a computer screen will strain the eyes.
- 10 Working under fluorescent lights makes the vision deteriorate.
- 11 Getting one's "second sight" — being able to read again without glasses — is a sign of good eye health.
- 12 Bifocals must be all the way across the bottom half of the lens for the best vision.
- 13 Lenses must always be tinted to protect the eyes.

- 14 Headaches are frequently caused by the wrong glasses.
- 15 The bifocals should always be at the same position for everyone if they are correctly positioned in the frame or lens.
- 16 Everyone will eventually need a trifocal.
- 17 Oral medications can never impair near vision.
- 18 Wearing contact lenses prevents eye deterioration, and if one is nearsighted, contact lenses will stop the progression of nearsightedness.
- 19 With contact lenses, one will need neither bifocals nor reading glasses.
- 20 Bifocal contact lenses or progressive bifocals are the two visual aids that work well for everyone.
- 21 If one cannot adjust to new glasses immediately, it means that the glasses are not right.
- 22 No one can walk down stairs, play tennis, nor play golf while wearing bifocals.
- 23 Proper diet usually improves one's eyesight.
- 24 Reading a lot creates the need for glasses and makes the eyes weak.

A comment about each of these myths is appropriate. It is interesting to look closely at them and perhaps gain some insights about how we think of our eyes and eyesight.

- 1 It is not true that putting off wearing glasses for reading as long as one can will be beneficial to the eyes. Those who do not wear glasses may not be fully aware of how helpful glasses can be and may deceive themselves into thinking their eyes are better than they really are. The lens within one's eye continues to grow throughout one's life, just as one's

fingernails and hair continue to grow, and as this lens within the eye grows it becomes less able to change its shape to focus for near vision, so everyone needs a different lens for near than for distance usually by the age of 50 or before.

- 2 One may get the impression that things do look blurred when the glasses are removed after they have been worn for a while. This is probably due to the fact that one realizes how much easier it is to see at near with the help of reading glasses.
- 3 Holding the reading material "too" close will not be harmful to the eyes. It takes more focusing effort to see something quite close. Small children have several times the necessary ability to focus for the usual reading distance and they are capable of holding reading material within two or three inches of the nose while still seeing clearly. As one gets older, this ability to accommodate gradually diminishes. The limitation of accommodation usually is such that one cannot read the phonebook without reading glasses in the fifth decade of life.
- 4 Sitting close to a television set will not be harmful to the eyes. Television screens now have a radiation filter on them, and the problem of radiation is no longer significant. The television image, like the image of a motion picture, is not damaging to the eye. If one looked directly into an eclipse of the sun, of course, this would be damaging to the eye.
- 5 Reading with just one eye does not put undue strain on that eye and does not cause any damage to the eye. Many people go

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through life with only one good eye and the functional lifespan of that eye is the same as that of a pair of eyes in a person able to use them both throughout a normal lifetime.

- 6 If one has glasses, he or she may want to go without them sometimes. It does not harm the eyes to wear glasses intermittently.
- 7 Anyone who needs a lens far near may have that lens made in a bifocal, or choose to have that lens as just a reading glass. A nearsighted individual who needs glasses primarily for distance may be able to read very well without glasses. Such a person has a built-in pair of reading glasses since his or her eyes are in focus far near and out of focus for distance, unaided.
- 8 Eye exercises will not improve visual acuity, and once someone is old enough to need a different lens for near than for distance, there is no way to restore the ability to focus by any type of therapy. Of course, one can look through a pinhole and see clearly at near because the light rays, coming straight into the eye through a pinhole, do not have to be focused and they fall on the retina with a clear image. However, the small size of the area seen tends to slow down reading considerably. In constricting the pupil by shining a light in the eye, one creates a pinhole-like pupil and this also may improve near vision. This is the reason why one at an older age can see better in a very bright light: the pupils are made quite small by this light and less focusing is required due to the nature of the optical system created.
- 9 Looking at a computer screen is not harmful to the eyes. It may be fatiguing to sit in one position for an extended period of time doing near work such as looking at a computer, but this is in no way harmful to the eyes.
- 10 Fluorescent lights are not harm-

ful to the eyes. A warm white color of fluorescent light is very similar to the incandescent spectrum of light. There are also some fluorescent tubes made to have a daylight-type light distribution that are said to be better for one's eyes than the ordinary fluorescent tubes; however, this has not been proven by any controlled studies.

- 11 Getting one's "second sight" — being able to read again without glasses — is a sign of poor eye health. It usually indicates that one is getting cataracts, and the lens within the eye is beginning to cloud in the nuclear portion in such a way that the eyes become nearsighted and the distance vision begins to diminish without



the proper correction.

- 12 There are several different styles of bifocals to provide good vision. It is not necessary for the bifocal to be all the way across the bottom half of the lens. Some bifocal styles are better than others, depending on the distance correction a person needs. The bifocals with a horizontal bifocal segment edge cause less apparent jump of the image when one looks from the distance segment down into the near vision segment of the lens.
- 13 The tint in a lens is a matter of personal preference. Obviously

when the light is bright, the pupils of the eyes constrict and this decreases the amount of light entering the eyes. Most of us are more comfortable with sunglasses when we are on the beach in bright sunlight reflected from the water or the white sand. The wearing of darkly tinted glasses indoors or in a dark environment may accustom one to this darkened lens so that he or she may find it hard to do without the tint comfortably.

- 14 Eye-related headaches are usually due to stress or fatigue and are rarely caused by the wrong glasses. When the glasses are not the best correction, then one does not see the best, but one may be perfectly comfortable and have no headaches.
- 15 The position of the bifocal in the glass and in the frame may be lower for the first pair of bifocals fitted than for the second pair. It is often easier to adjust to a pair of bifocals in which the bifocal segment is positioned a few millimeters lower than may be ideal later when the patient has gotten used to having the bifocal segment there. More often than not, one finds it convenient, after getting used to bifocals, to have the bifocal glass segment in a position that requires a minimum of chin raising to look through the near segment. Sometimes, a frame with an adjustable nose pad is useful so that the position of the bifocal can be changed by raising the frame on the face.
- 16 With use of a progressive bifocal, one may never need a trifocal, because the progressive bifocal is a multifocal lens with intermediate focusing ability as part of the lens system. Others may never need excellent vision at an intermediate distance and will always be satisfied with the bifocal kind of glasses. Any bifocal is a compromise between focal length and magnifying power far near; and as one gets older, one usu-

- ally has to sacrifice range of clear near vision for more magnification from the bifocal segment.
- 17 Some oral medications may impair the ability to focus. It is best to read the brochure in the medication packet to determine if blurred vision is reported as a side effect of the drug.
 - 18 There is nothing therapeutic about an ordinary contact lens in preventing the progression of nearsightedness. If the cornea has been molded by a contact lens, the cornea will resume its previous shape after a short interval of not wearing the lens.
 - 19 Those who wear contact lenses for distance will need reading glasses over the contact lenses for near when they become old enough to have difficulty focusing. It is not unusual for contact lenses to be used to correct one eye for near vision and the other eye for distance.
 - 20 Bifocal contact lenses and progressive bifocals are not satisfactory for everyone, but there are some individuals who function very well with these optical aids. Progress is being made in design of bifocal contact lenses. A lens that will work for more people is anticipated.
 - 21 It may take several weeks or months to adjust to a new pair of glasses, particularly if there has been a marked change in the power. The introduction of a cylindrical component to the lens for the correction of astigmatism requires some adjustment. While most people can adjust to a bifocal, there are those who seem to be unable to do it even though they may try.
 - 22 After becoming accustomed to having some blurred vision at one's feet through the bifocal, one can learn to function in a tennis match or a golf game with bifocal glasses. However, many people prefer a pair of glasses without the bifocal for playing sports.
 - 23 Eating carrots or using some very special diet has not been demonstrated to be therapeutic in this country where for the most part there is not a problem with vitamin deficiency.
 - 24 It is not true that reading a lot creates a need for glasses. Fatigue may be a problem with prolonged reading; however, just as one does not strain the brain by thinking, one does not strain the eyes by using them.
- It has been interesting to note that there has been an especially high demand for eye evaluations during the period of final exams on campus. It seems that probably the greatest difficulty is from the stress of the finals, possibly from the students' lack of timely preparation for them. Most of the eye symptoms seem to disappear after exam week only to recur at the next time of general stress. □

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National Study Shows Generics Not Necessarily a Better Buy

Generic drugs aren't always cheaper.

A recently published study in the *Journal of the American Medical Association* reveals that despite the advertising claims of companies that produce generics, prescription generics are not universally less expensive to consumers than their brand-name counterparts. Even when they are, the study finds, consumers must spend considerable time and money searching for the best buy because of wide price variation at drug stores.

"Saving money at the pharmacy counter has been touted as the sole advantage of generics over innovator products, but the savings just aren't there in every case," said Bernard Bloom, Ph.D., study investigator and research associate professor at the Leonard Davis Institute of Health Economics of the University of Pennsylvania. With some drugs — for example, Lasix and furosemide, or Premarin and conjugated estrogens — Bloom said that the generics cost more than the brands two-thirds of the time.

"Although the cost per pill paid by pharmacies is less for generics, that reduced price isn't always passed on to

the public," Bloom continued. He pointed out that states mandating that generic drug savings be passed on to the consumers actually had a higher price per pill for both brand and generic than states that don't require pass-through.

The study also shows that consumers must shop extensively to obtain the lowest-cost prescription and weigh expected savings against the cost of this search. "In fact, consumers can never know whether they're getting the lowest price," Bloom pointed out. Prices fluctuate between pharmacies and within individual stores. The study further finds that pharmacies mark up generics more than comparable brands and realize a greater profit from generic sales more than half the time. "If the consumer can't be guaranteed the lowest price by buying generic, the reason for accepting a substitute product quickly evaporates," Bloom said.

The study in *JAMA*, funded by a grant from Ayerst Laboratories, reviewed pricing for 891,866 prescriptions written for 21 pairs of branded and generic drugs dispensed between April 1 and June 30, 1984. It involved 1,363 pharmacies — both chain and independent — in 39 states and included such widely prescribed drugs as Lasix (furosemide), Premarin (conjugated estrogens), Indocin (indomethacin), and Librium (chlordiazepoxide).

What Is a Hospital Chaplain?

P. Wesley Aitken

The practice of having clinically trained clergy in hospitals dates back to the late 1920s and the early 1930s in some of the Northeastern states. However, the surge of interest in hospital chaplaincy came in the late 1940s following World War II. As Veterans Administration hospitals were built, the military model of chaplaincy was transferred into them and all of those who filled the positions at that time were former military chaplains.

The earliest programs in private North Carolina hospitals were at Baptist Hospital in Winston-Salem and then Duke University Hospital in Durham. The Baptist Hospital had chaplains on its staff as early as 1946 and began clinical training programs for clergy in 1947. Duke Hospital began its chaplaincy program and its clinical training program for clergy in 1956.

Today, just about all of the larger hospitals in the cities of North Carolina and also the county hospitals have chaplains on staff. Even so, some people still ask the old question, "Why should a hospital have a minister full-time on the staff when there is a continual stream of community ministers in and out of the hospital every day?" It might be timely to attempt to answer that question once again and to review the status of the movement.

Helping the Patient Cope

As health care professionals have fought diligently to increase the quantity of life for people, there has been growing concern on the part of

health professionals and allied health professionals for the quality of life both during the hospital stay and also once the patient has returned home. When we study seriously the quality of life patients live while in our hospitals, we realize that not only is quality of life capable of increasing or decreasing the actual quantity of life, but the way a person copes with an illness while hospitalized can speed or slow the recovery. It follows then that if a patient makes healthy effective use of his or her religious beliefs and philosophy of life while coping with the adversities associated with illness, the quality of life while in the hospital can be improved and the length of stay in the hospital might be shortened.

Some of the great questions of life, such as those surrounding suffering, are asked and answered repeatedly throughout one's life. The answers may change but the questions always remain the same. Some of these great questions predictably confront people once again when they become ill. The questions take this form:

Something is happening to me that bothers me, makes me uncomfortable, causes me pain or limits my ability to function. I don't like it. Can I change what is happening to me?

If I can't change what is happening to me or get control over what is happening to me, can my physician?

If I can't change or get control over what is happening to me, and my physician can't, who is in control of what is happening to me?

Who or what is either causing this or letting this happen to me? Why?

Does this power or control that is beyond me and my physician like me or dislike me?

Can I affect or influence in any

way this power or control which is beyond me and my physician?

What is my relation to this power or control and what should be my attitude toward it?

Most people turn to their religion and philosophy for the answers, and there are about as many answers as there are people. The answers do fit into general categories, however, and take rather specific forms. It is the expertise of the hospital chaplain (a clinically trained clergyperson) to help people struggle with the questions and find answers that are reasonably satisfying to patient and family.

Why Have a Special Chaplain?

In contrast to the hospital chaplain's approach, community clergy who are related closely to religious groups such as churches and synagogues are personally committed (and feel some obligation) to give the answers embraced by their respective religious groups. This is an important difference between a hospital chaplain and a community clergyperson.

To elaborate on it just a little more, some community clergy feel an obligation not only to tell the patient there is only one set of answers but also to stress that if the patient does not accept those specific answers he or she will not get well and will be damned. Hospital chaplains do not give answers, they help patients and family struggle with the questions and find their own answers.

It is obvious that there could be Jewish answers to the questions as well as Protestant Christian answers or Fundamentalist answers or Hindu answers or Moslem answers or even atheist answers. The questions do not change, only the answers change.

From the Director, Chaplains Service, P.O. Box 3112, Duke University Medical Center, Durham 27710.

Hospital Chaplains' Clinical Training

What constitutes the clinical training received by the hospital chaplain? As early as 1925, Dr. Richard Cabot, a renowned physician at Massachusetts General Hospital, advocated that all clergy, like physicians, be required to take a clinical internship. He believed it would enrich ministry even at that day and time. Today, if a clergyperson wants to qualify as a certifiable hospital chaplain by the national "College of Chaplains," that person must have completed at least a twelve-month clinical internship.

The clinical training programs for clergy are nationally standardized and nationally accredited as clinical pastoral education programs by the Association for Clinical Pastoral Education in Atlanta, Georgia. Students are selected rather carefully. If an applicant is an enthusiastic advocate of a specific or exclusive set of answers to the questions mentioned above, that person is not likely to be a good candidate for Clinical Pastoral Education and hospital chaplaincy. That person would not be free enough to allow a patient to arrive at a set of answers different from those zealously claimed by the student. A good candidate for Clinical Pastoral Education and hospital chaplaincy should be comfortable enough with his or her answers to the questions and familiar enough with the struggle to achieve those answers that he or she would be willing for a patient to arrive at different answers.

Following the selection of the candidates, the students are placed in small peer groups (maximum of six)

and are required to begin functioning as hospital chaplains after some basic orientation and limited training. By the end of the first week the student is on the ward functioning as a student chaplain under close supervision. Each group has its own clinical supervisor, and the six-member groups will meet with their supervisors at least twice a week in order to reflect upon the efforts to counsel and help people. There are also individual supervisory sessions so that each student gets close support and close surveillance with yet enough freedom to work on the wards and function as chaplain.

The didactic studies of the student can be in a variety of areas but certainly some training in counseling and psychology and in stress and grief will be required. In order to qualify for Clinical Pastoral Education a student must have completed or be nearing completion of his or her formal theological education. As a physician must go to medical school and then do a clinical internship, so must a chaplain go to divinity school or seminary and then do a clinical internship.

The Extent of Need

Not all patients or family members need the specialized assistance of a hospital chaplain. As many as 85% of the patients and family members will handle their hospital experiences without difficulty by making use of their relationships with their physicians, general hospital staff, family and home people including their clergy. Approximately 15% of the patients will need specialized assistance. This will vary somewhat ac-

cording to the individual hospital and the type of care that it provides.

In addition to helping patients and family members, chaplains are available to staff and hospital personnel for counseling usually limited to patient care issues. This includes facilitating grief and assisting in stress management. Hospital chaplains also often serve in some capacity on hospital ethics committees and patient care committees. They are the liaison with the religious groups and the clergy of the community.

If more than one chaplain is needed, a hospital can turn to community clergy for backup. If more extensive and around-the-clock coverage is needed, it is wise and economically advisable for a hospital to consider employing one senior staff chaplain who is certified as a supervisor of Clinical Pastoral Education and then fund the tuition of the chaplain interns or residents as payment for services rendered. In this way, a hospital can obtain a very high quality of chaplaincy for the salary of one senior staff chaplain. In a sense, a hospital can get four or five chaplains for the price of one.

The economics of health care has forced cuts in some hospital chaplaincy programs. However, I believe hospital chaplaincy is here to stay. It makes a significant contribution to the total health care provided by institutions if only through bedside conversations helping patients and families cope. The religious rites, sacraments, and ceremonies also provided or arranged by the Hospital Chaplain are important, but the principal contribution will always be the pastoral conversation and counsel. □

Announcement from the AMA Auxiliary

A series of booklets focusing on the special concerns of medical families is being published by the American Medical Association Auxiliary. This series is part of the AMA Auxiliary's ongoing effort to provide education and support on issues affecting the lives of physicians' spouses and their families.

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Policing the Practice of Medicine

Eugene W. Linfors, M.D., editor

- *The question for February is: "Should our Medical Society play a greater role in policing the practice of medicine?"*

From Harold L. Godwin, M.D., Medical Director, Fayetteville area health education foundation.

I have three suggestions for a greater role in policing the practice of medicine by the North Carolina Medical Society. I suggest it continue to encourage the passage of legislative proposals brought by the Board of Medical Examiners in the spring of 1986. I also suggest that the society encourage a more forceful role of local peer review by appropriate county society committees and hospital staff groups. My third suggestion will follow some observations about the Board of Medical Examiners.

On the board for 12 months, I am now reasonably knowledgeable about its procedures. The administrative staff is first-rate and the Board convenes frequently and for very long intervals. Discussions end with well deliberated, firm but compassionate conclusions based always on the concrete yardstick: "Would this be acceptable medical practice for my family?" The majority of Board activities are never apparent because informal interviews are always held behind closed doors.

The Board operates under many investigative and disciplinary restraints which both the medical and general public erroneously assume are ordinary Board prerogatives. Only licensed physicians come under Board jurisdiction and this means that even flagrant malpractice activities of non-physicians are not subject to the medical examiners but rather to the Attorney General's Office. There they are a low priority when compared with other more weighty legal matters and often simple fines of \$25 result and the activity may resume. There are also many M.D.s who are not members of the medical society nor of any hospital staff. Medical transgressions in this arena are difficult to uncover unless informants are forthcoming. Informants, contrary to general misunderstanding, always remain confidential.

My third suggestion involves a reversal of the current method of handling the physician who is abusing substances, himself, his patients or all three. Now, discipline is first and help is second. I feel strongly that this should be turned around. The concept is not new and has been extremely successful in other states. Our present system depends primarily on the donation of interest and time by members of the society's Physician's Health and Effec-

tiveness Committee. As the numbers grow, this is obviously unfair to the Committee, unwieldy for the Board and unwise for the sick physician.

Funding for a new approach to the impaired physician is an obstacle which must be overcome. In this connection, the leadership of the Medical Society and the Board of Medical Examiners are discussing a joint venture and it is my hope that this will be quickly endorsed by all concerned.

From A. Eugene Douglas, M.D., a psychiatrist in Lumberton.

The question posed by this month's Physicians' Forum is to say the least quite difficult. I feel that the answer to the question is yes, however, I am not at all sure how this can be accomplished but will offer the following thoughts. Currently the North Carolina Board of Medical Examiners does an excellent job of dealing with physicians who "break the law." The Impaired Physicians Committee of the North Carolina Medical Society is making a significant impact in dealing with impaired physicians. These are physicians who are primarily substance abusers. Hospitals generally monitor quite carefully privileges, credentials and through quality assurance activities, length of stay, pathology reports, etc. In most areas the hospitals are identifying problem areas and ways of managing these problems. The possible exception here is that there are many free-standing psychiatric hospitals where the main order of business continues to be "cashectomies." We are all familiar with PSROs, PROs, etc. and again they have been effective in some areas but have subjected the conscientious and ethical practicing physician to what might best be described as "harassment." A recent letter to the editor in the *North Carolina Medical Journal* by James A. Bryan II, M.D., eloquently speaks to that issue (1986; 47:281).

What seems to be missing is an acceptable forum within which the general public can express concerns about medical care. These concerns have to do with accessibility, competence, quality of care, appropriateness of care, cost of care, etc. It is true that the medical society has a grievance committee that can address these issues, however, the public is not generally aware of that procedure.

Would it make any sense for the North Carolina Medical Society to actively initiate a "PR" campaign to inform the general public that there is a process by which their

concerns can be addressed? Many complaints would undoubtedly be petty and inappropriate but some would not. Might the general public perceive this as a genuine effort on the part of the medical community to "police" itself?

Many will have objections and perhaps they are right. However, alternatives are even more bleak. I feel that the general public will continue to pressure the political structures to develop additional PSROs, PROs, DRGs, etc., and that eventually the political system will respond with more and more controls ultimately leading to a socialized system of medical care much as exists now in Britain. I personally do not believe the political structure is the answer, but you can be sure it will provide the "the answer" if we do not.

The medical society proposes to spend millions to "lobby" for tort reform in reference to the malpractice crisis. Could this money be better spent convincing the general public that we as physicians are concerned and willing to develop an appropriate forum for these concerns? There could be no better lobby than a return to the days when the medical profession was considered an essential and honorable profession.

This concept is probably far too idealistic in view of the historical traditions of the medical profession of fraternalism and protectionism. However, failure to satisfactorily address this issue will inevitably further reduce our credibility.

From Martin L. Brooks, M.D., a physician in Pembroke.

There is little wrong with the practice of medicine today that a good dose of honesty would not fix. Awareness of our limitations as human beings and as physicians and acceptance of those limitations could go a long way in establishing a brotherhood among physicians and their fellow travelers (patients).

As I see it, one of our most effective ways of policing ourselves is by taking a greater leadership role in educating our patients (good followers make good leaders).

When President Truman was asked about appointing an ethics committee for the U.S. Senate, he whipped back, "What is wrong with the Sermon on the Mount?"

We physicians might do well to ponder the same question and seek individually and collectively to be more like the man Luke referred to as "The Beloved Physician."

From Thomas E. Fitz, M.D., an internist in Hickory.

As I have just gone off of the Board of Medical Examiners (after six years of service), I have strong opinions relative to the need for our Medical Society to play a greater role in policing the practice of medicine in our state. One would have to be knowledgeable of the Board of Medical Examiners' activities, both their informal and formal, to see the need for greater participation. Unfortunately, not all of our practicing physicians are members of our Medical Society.

This brings me to how the society could play a role. As the society is made up of individuals, each member should consider it his or her responsibility or duty to uphold the highest standards of medical practice. Whenever anyone

is knowledgeable of acts or activities not consistent with the highest standards, he or she should be willing to stand up and be counted. By this I mean one could act on the local county society level, friend-to-friend level, etc., and confront the individual as to the problem. Whether it be substance abuse, incompetency, unprofessional conduct, these should be pointed out and actions taken. One should not hesitate, after the facts are established, to report these individuals, if necessary, to the Board of Medical Examiners. On the other hand, there is a hesitancy "not to become involved," and the Board's action may well be hampered. If the Medical Society could arouse the responsibility of the individual to work for the good of all, then policing the practice of medicine by our Medical Society might well be of value. As I understand it, policing means to gather information. I feel that with that information obtained, then the decision as to what to do with it remains. It is the Board of Medical Examiners' responsibility to act on that information. The Board can only act where there is a willingness for "witnesses" to testify.

There has been a good working relationship between the North Carolina Medical Society and the North Carolina Board of Medical Examiners. I should think that this could be continued and strengthened.

From Eban Alexander, Jr., M.D., a surgeon at Bowman Gray School of Medicine in Winston-Salem.

The answer to the question is "yes."
How?

1. A) The North Carolina Medical Society can pass resolutions recommending for or against forms of treatment or health hazards which can and should influence medical practice.

The best example of that is the resolution passed some years ago concerning the inadvisability of using amphetamines and other appetite suppressor drugs for weight loss.

This particular resolution has had a significant impact on the practice of medicine in North Carolina particularly because of the use of this resolution by the North Carolina Board of Medical Examiners.

B) The North Carolina Medical Society shares responsibility for judgment concerning physicians practicing in North Carolina who make excessive use of alcohol or other drugs. This is a relatively small number of physicians but the state medical association has taken a strong position in its "impaired physicians program." This position needs to be stronger, supported by better financial background, and made truly helpful to physicians impaired by the use of alcohol and/or drugs. Such physicians are not only a threat to themselves but to the patients for whom they care.

The North Carolina Medical Society does and should to a greater extent support the functions of peer review efforts by the hospital staff of various hospitals of the state.

The North Carolina Medical Society should continue supporting in every way it can the disciplinary functions of the grievance committees of the county medical associations.

In addition to this, every individual who is licensed to practice in North Carolina is interviewed by at least one member of the Board of Medical Examiners or the Ex-

ecutive Director of the Board before a license is granted. If there is a question in the minds of the single examiners, that applicant is asked to appear before the entire Board of Medical Examiners at its next meeting.

The North Carolina Medical Society should seek to support in every way it can the strengthening of the function of the N.C. Board of Medical Examiners by advocating and lobbying for changes in legislation to give the Board of Medical Examiners powers to enforce its judgments on an equitable basis.

The Board of Medical Examiners is concerned with many major problems:

1. alcoholism
2. drug abuse
3. illegal prescribing habits by physicians
4. the committing of a felony
5. the committing of a fraud
6. criminal activities of any sort
7. medical incompetence
8. abetting the illegal practice of medicine by those not licensed as physicians
9. sexual intimacy with patients
10. overcharging of patients
11. notice of disciplining or discharge from a hospital staff

In all of these matters, the Board gives prolonged consideration to each subject brought before it with the aid of competent legal assistants.

In conclusion, it is of utmost importance that the judicial system of North Carolina support the confidentiality of peer review: records at the hospital level, the local medical society level, the state medical association level, and the North Carolina Board of Medical Examiners.

From Charles H. Duckett, M.D., a practicing physician and faculty member at East Carolina University School of Medicine in Greenville.

Through its constitution, the medical society represents the physicians of the state and is provided the responsibility to elevate the standards and quality of care provided to patients by those physicians. Therefore, it is an innate responsibility of the medical society to assist in "policing" the practice of medicine in our state.

The Board of Medical Examiners is the body established by statute to properly regulate the practice of medicine and surgery and to protect the well-being of the citizens through its actions. The methods for formal disciplinary proceedings, however, are cumbersome and time-consuming, and often the Board is able to address only the major problems while multiple lesser problems may not be addressed adequately through early intervention and a "preventive" approach. Though the medical society is active in some investigation of complaints and allegations relating to physicians, the methods to do more could be expanded through legislation which would provide proper protection from liability.

A major need for reporting and follow-up is in the area related to the impaired physician, including those who are physically or mentally ill, dependent upon alcohol and/or

drugs, or too cognitively incompetent to practice safely. Currently, the Health and Effectiveness Committee of the medical society has a number of diligent physician volunteers who spend untiring effort in the rehabilitation of impaired physicians. But, these volunteers could be much more efficient with a central organization, including at least a physician and a secretary, to provide the continuity of contact and follow-up that the impaired physician needs for successful recovery. Special treatment centers might be developed and supported by the medical society at a later time.

This is but one example of how the medical society can be helpful in identifying and assisting the impaired physician to recovery. The Board of Medical Examiners can also assist the medical society in this sense, but the Board is the body that must retain the responsibility for mandated corrective and probationary action. The concerted effort of both to maintain the quality of care of patients at a level of excellence should be the goal. Yes, the medical society through its collective membership should play a greater role in policing the practice of medicine in our state.

From E. Harvey Estes, Jr., M.D., an internist at Duke University Medical Center, Durham.

The North Carolina Medical Society plays an important role in a certain type of "policing," but it has severe limitations in other types.

In the area of poor communication between doctor and patient, the medical society, through county and state society mediation committees, serves a very useful role, which could be made more important by publicizing this activity more widely. These conflicts usually involve fee disputes, lack of response to requests for records, and similar matters. The parties involved have reached an impasse, but remain receptive to an outside mediator. The doctor is often not aware of the dispute, which has been carried on by members of his office staff. An opinion by the physician's peers is generally appreciated and honored by the two parties, relieving the tensions and avoiding litigation.

These disputes are usually relatively minor in severity and represent misunderstandings between rational and reasonable people.

In other "police" actions, the medical society is almost helpless. There are physicians whose activities are at the fringes or beyond the bounds of ethical or scientific practice, and who are usually fully aware of this fact. They continue their activities because it is profitable, or it is the only type practice they know.

In such cases the medical society is almost totally impotent. These offenders usually have little regard for peer opinion. The only way to offset their behavior is by application of sanctions — fines, prison sentences, denial of privileges, withdrawal of licenses, etc. The medical society has only one sanction at its disposal — ejection of the offender from its ranks. This is usually an ineffective gesture.

The only effective organizations for this type of policing are those capable of imposing sanctions — hospital boards, licensing boards, and criminal courts. When the medical society attempts to deal with this type offender, it also

opens itself to litigation, without the legal protection available to the above groups.

It is my belief that a better course of action is for the medical society to refer these cases to the Board of Medical Examiners, or hospital medical staffs, for further investigation and action.

From Charles R. Vernon, M.D., a physician in Wilmington.

The answer is, "Yes and no."

Yes, NCMS is vitally concerned with quality of medical practice. The fundamental professional interest of each physician and thus NCMS is the health of the individual, the family, and the community. This interest and concern are best served by the Society's supporting peer review and continuing education. Where there is evidence of poor quality of care the interest of NCMS is in providing help and support to improve the standard of care of the physician involved, complementing local mechanisms within county medical societies and/or community hospitals. Re-

dress would be by appropriate prescriptive remedial education or prescriptive treatment and rehabilitation, and in some instances both, orchestrated through an appropriate existing committee (like the committee on physicians' health and effectiveness or committee on medical education). A monitoring system, such as already exists in the committee on physicians' health and effectiveness, should be provided for an extended period of time. This can be implemented by expanding and extending existing resources within the society, again, complementing local resources.

No, NCMS should not be in the business of policing the practice of medicine in our state. The Society is an organization based on a collegial relationship, not a big brother one. And our interest is not just in being sure there is a minimum standard of care. We are interested in a high standard of care, with consideration of cost, but dictated by best quality, by the best interest of the patient.

"Collegial" is the proper word in this context. We are all teachers and learners, and the Society is obliged to provide a means to promote the teacher and learner in each of us, please!

- *Editor's Note: Careful readers of our opinions this month will be aware of what the North Carolina Medical Society is already doing to police the practice of medicine as well as some good suggestions for an expanded role. The message from our respondents would seem to be that the medical society can and should support good faith efforts to identify and help the impaired physician, local attempts at peer review, and the establishment of a forum for the general public to express concerns about medical care.*



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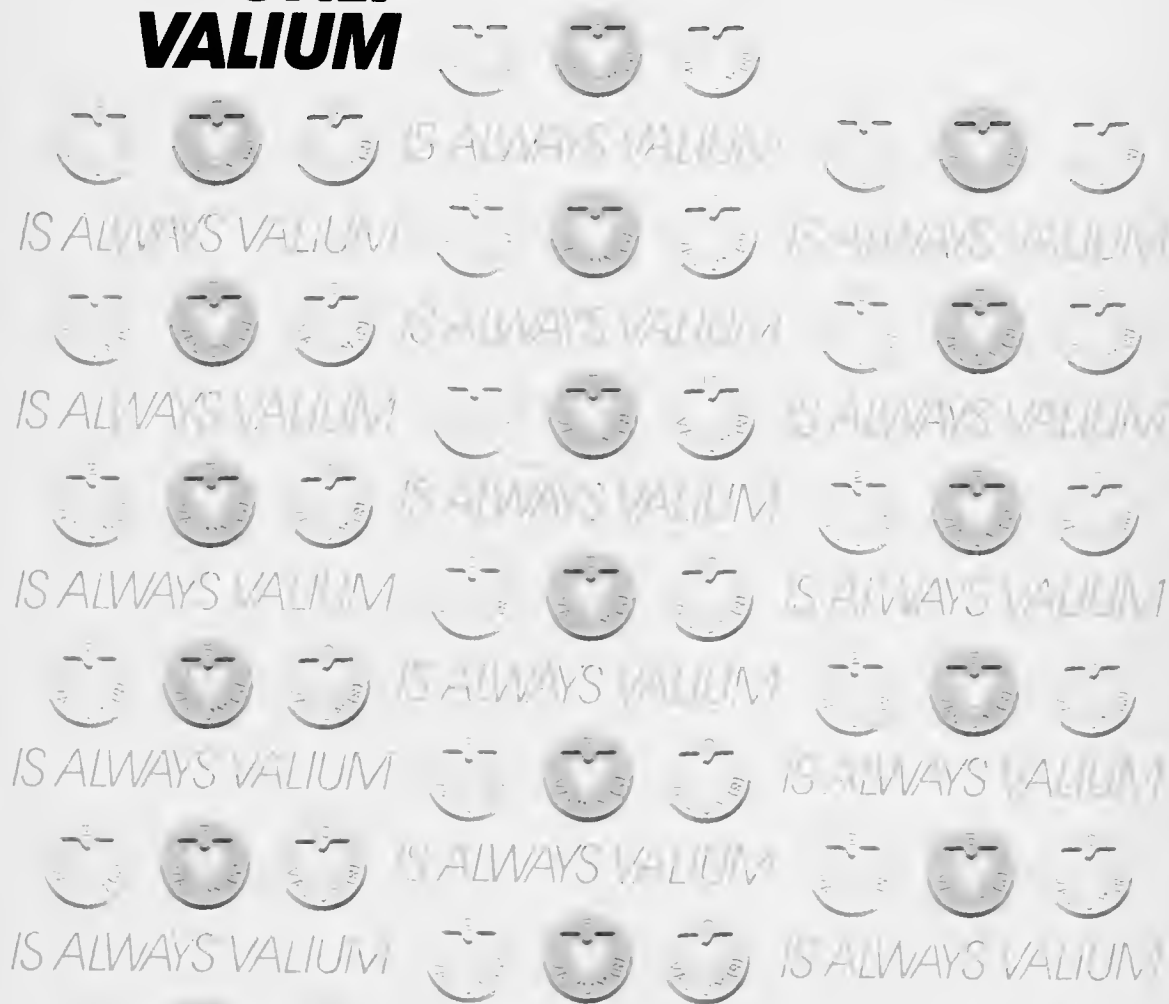
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The View from the Bed

Mark W. Swaim

DOCTORS are bad patients, but medical students are worse. Textbook knowledge is our undoing. We know what *might* be wrong with us and confront our own aches and palpitations with abject terror.

I began caring for patients never having been one. I approached suffering with both compassion and the confident naivete of one who never has suffered, who takes his own health for granted — hospitals, after all, are for *sick* people. My white coat was for me a subliminal guarantee of immunity to illness. *House of God* Rule Number IV: The *patient* is the one with the disease.

When I doubled over with monumental abdominal pain this summer, the inviolability of my health ended abruptly. Lab-mates whisked me off to the emergency room where I became, for the first time, a patient. I was terrified. Did I have a twisted or obstructed bowel? A kidney stone? A perforation or rupture?

A year ago I had worked in this same ER caring for terrified patients on stretchers. Now I was on a stretcher, writhing and panting in excruciating pain, being wheeled to a familiar radiology suite for emergency x-rays of my belly.

A resident reinforced my worst fear: "Looks like you may have perfed." A perforated intestine . . . a hole in my bowel . . . peritonitis . . . emergency surgery. I wanted someone to read the riot act to my raging innards.

Medical students who become patients are afforded red-carpet treatment, cared for by their professors. A graying, bearded man in a white coat came to my bed.

"Hi, Mark, I'm Dr. S." I knew he was chief of the emergency room, and he meticulously examined my abdomen. "Your x-rays aren't back yet," he said soothingly.

Suddenly I was seized with a searing spasm deep in my viscera. "I can't stand it!" I screamed, groping at my belly. I pleaded for pain medication.

Dr. S. squeezed my hand. "Mark! MARK! You're a medical student! You know we can't give you anything until we know what's wrong."

Sobbing, with teeth clenched in agony, I nodded.

I had forsaken all reason. I had become like a colicky horse that injures itself by thrashing in pain and panic. I was ready to commit *seppuku* with the nearest scalpel.

"Physician, heal thyself" mocked me.

"I'm having the nurse draw blood and start an intravenous," Dr. S. said. "I'm also sending a surgeon in to look at you."

I winced as the nurse plunged an eighteen-gauge needle deep into my forearm. I had started i.v.s many times and knew what came next. I felt warm blood trickling onto my forearm.

After what seemed an eternity, I learned my x-rays had appeared normal except for a small bowel inflated like a balloon. "Looks like bad bowel spasms, but you haven't ruptured anything," the resident said. The next hours were a ritual of rectal and intestinal indignities, familiar if you're a doctor, painful if you're a patient.

Five hours after I had arrived at the emergency room, my bellyache began to subside, gradually, as mysteriously as it had come. Exhausted, I dozed as fluid dripped into my veins.

The doctors were baffled. Had I passed a kidney stone? No, the pain wasn't the right kind and my urine was normal. A twisted bowel? Maybe, but the pain had gone away. Food poisoning? Maybe, but I had no fever or nausea. Merely severe intestinal spasms? Probably, but why?

I left thinking about an OB-GYN resident I knew who, having given birth to her first child, swore she'd never deliver a patient's baby the same way again. Likewise, I am sure I'll never approach patients the same way again.

For most of us, health is like stage lighting: we notice it only when it's bad. I've learned to appreciate the absence of pain, and that some things I do to patients *hurt*. Needles are bigger on the receiving end. And bedpans are embarrassing. I've put these experiences into a mental Rolodex to help me view patients from the bed instead of only from the bedside.

I realized pain can turn anyone into a gibbering heap. Within half an hour of my attack I had become a Whitman's Sampler of fears: fear of dying, of surgery, of disease, of future impairment. Three years of medical education suddenly counted for naught, and "Will I be okay?" became a far more pressing concern to me than any diagnostic challenge I posed.

I learned more in one afternoon than in any medical school course, and I left the hospital understanding for the first time why the wounded physician is the best healer.

I had gotten my comeuppance, as Orson Welles said of George Amberson, "three times filled and running over."

□

From Duke University Medical Center, P.O. Box 2789, Durham 27710. Previously published in the Spectator Magazine of the Triad, August 14-20, 1986.

Remembering Bonnie

Richard D. Kenney, M.D.

I had seen Bonnie a number of times over the years before she turned 13, for the typical office visit problems: upper respiratory infection symptoms, camp physicals, a rash. She would sit on the exam table, speaking only when spoken to, taking her cues from Mom, who was "raised right," being always deferential and courteous.

Shortly after school restarted, Bonnie came in because of a stomach ache of two day's duration. She didn't look ill, sitting in her compliant way. Mom's placidity gave no clue of concern. The history was not helpful. During the physical exam, I saw a well-distributed female escutcheon and axillary hair. "Better do some more checking," I thought.

"Bonnie, would you please loosen your bra so I can check your breasts?"

"Is there a problem, doctor?"

"No, Mrs. P., just checking. Have you seen your period yet, Bonnie?"

"No, she hasn't, doctor, but we've talked about it."

"Well, getting back to the abdominal pain, I don't find too much. Maybe it's a viral illness starting up. Let's just check the urine to be sure it's not an infection in the kidney system."

"That's fine, because she did vomit the last week or so. Didn't I hear you when you first got up, Bonnie?"

"Yes'm," shrugged Bonnie.

"OK, let's check the urine. I'll be right in after we do that. I'll ask my nurse to help you."

Allowed only the time that most pediatricians have to construct an explanation for a patient's symptom, that time between exam rooms, I wondered if she could be pregnant. She was premenarchal but her physical sexual maturity was worrisome. Could the vomiting be morning sickness? I thought I'd better ask some more questions. In the meantime, I ordered a pregnancy test.

Thirty minutes later: "Doctor K., here is the result on

that urine you ordered." Urinalysis — negative. Pregnancy test — POSITIVE.

Yikes! Little meek Bonnie?! She hasn't even had her first period yet! Can I trust this test?

Well, I went back in, asked Mrs. P. to leave and talked with Bonnie.

After a few tangential inquiries that gave me no response, I said, "Bonnie, I don't know if you know it or not, but we sometimes use a urine test to find out if someone is pregnant. When we did your test, it came back positive. Do you think you could be pregnant?"

Teenagers talk with their eyes, with their bodies. "Me?" she shrugged, with an expression that indicated I was way off base. "I haven't had a period yet."

"You're right. It would be unusual. Have you been with anyone in the past two or so months?" I deliberately left out the verb, "sleeping," for teenagers can't conceive of having such a luxury.

"Whaddya mean?"

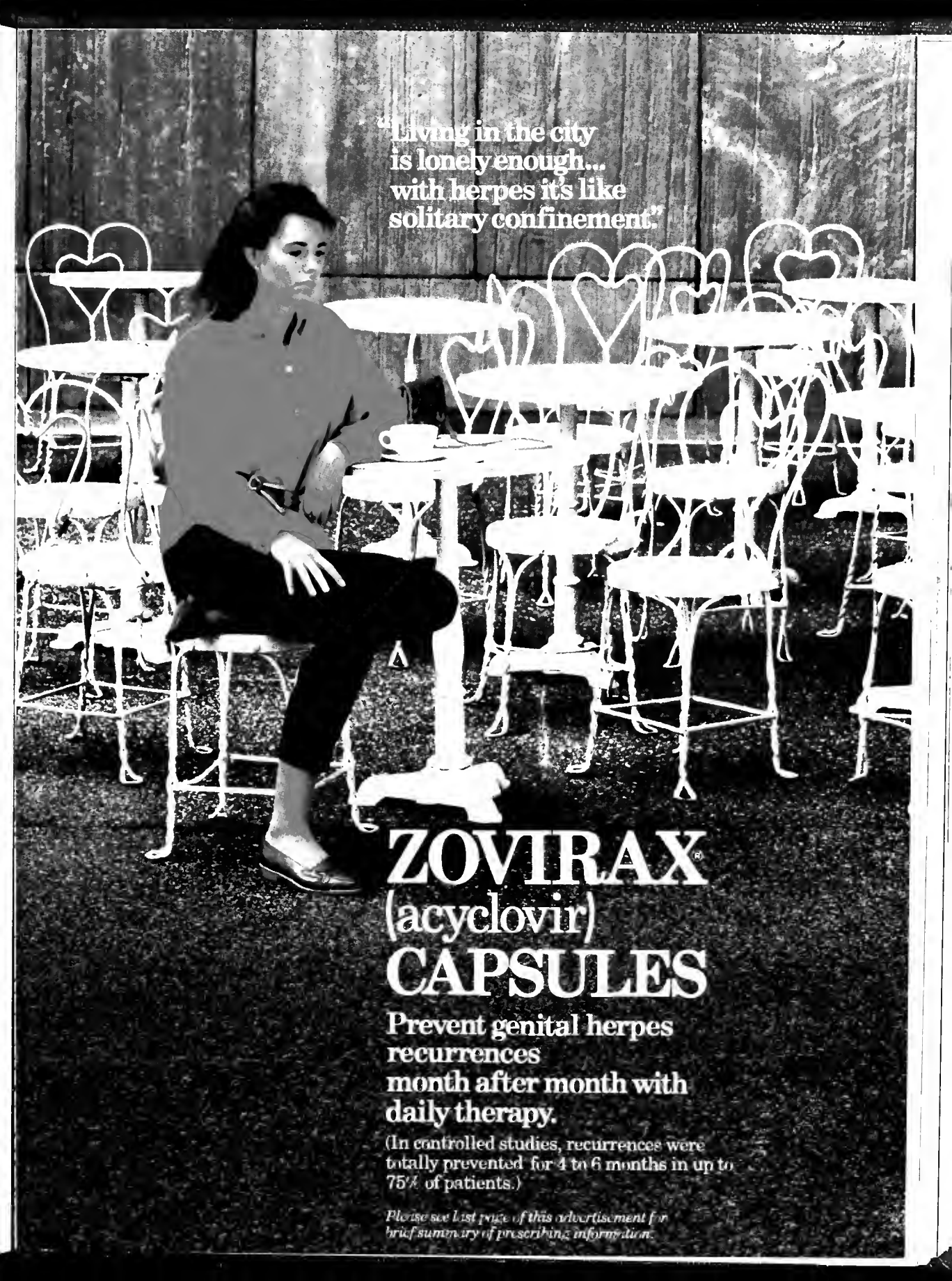
"Have you had sex with anyone?" Another euphemism they have no concept of is "making love."

"During the summer, this guy I met, Larry, and I were kissing and stuff. Just fooling around."

Seems like a lot of that goes on — fooling around. More than a little truth in that phrase, considering how foolish it is and how they are only fooling themselves. This premenarchal girl had gone from no menses because of her developmental age, to no periods because she was pregnant.

Bonnie taught me all right. Anyone who is physically capable of becoming pregnant can be. In the adolescent age group, if the complaint is vague, the history doesn't mesh with physical exam, or the problem is genitourinary, consider a pregnancy test. I've learned that patients like Bonnie will come in with aches and pains, intermittent abdominal pain, or malaise. On those occasions when I have hurried an interview or allowed myself to be convinced that pregnancy is an unlikely possibility, I have soon regretted not remembering Bonnie. □

From the Department of Pediatrics, Charlotte Memorial Hospital & Medical Center, Charlotte 28232



"Living in the city
is lonely enough...
with herpes it's like
solitary confinement."

ZOVIRAX[®]

(acyclovir)

CAPSULES

**Prevent genital herpes
recurrences
month after month with
daily therapy.**

(In controlled studies, recurrences were
totally prevented for 4 to 6 months in up to
75% of patients.)

*Please see last page of this advertisement for
brief summary of prescribing information.*

ZOVIRAX[®] **(acyclovir)** **CAPSULES**

**Help free your
patients from
recurrences.**

Daily therapy

Coping with genital herpes is rarely easy. For some, the worst part is the pain and discomfort of frequent attacks — month after month, year after year. For others, the emotional burden presents a more difficult problem, leading to social isolation, anxiety, and diminished self-esteem.

Prevent or reduce recurrences

Although your patients have to live with herpes, they shouldn't have to suffer. Daily therapy with ZOVIRAX CAPSULES can help free them from the cycle of recurrent genital herpes. For many, one capsule three times a day can suppress recurrences completely while on therapy.

Generally well tolerated

Daily therapy with ZOVIRAX CAPSULES is generally well tolerated. The most frequent adverse reactions reported during clinical trials were headache, diarrhea, nausea/vomiting, vertigo, and arthralgia.

The physical and emotional difficulties posed by genital herpes are unique for each patient. The frequency and severity of recurrent episodes, as well as the emotional impact of the disease, should be considered when selecting daily therapy with ZOVIRAX CAPSULES.

*Please see brief summary of
prescribing information on next page.*



Prevent recurrences month after month* **ZOVIRAX®** (acyclovir) **CAPSULES**

Brief Summary

INDICATIONS AND USAGE: Zovirax Capsules are indicated for the treatment of initial episodes and the management of recurrent episodes of genital herpes in certain patients.

The severity of disease is variable depending upon the immune status of the patient, the frequency and duration of episodes, and the degree of cutaneous or systemic involvement. These factors should determine patient management, which may include symptomatic support and counseling only, or the institution of specific therapy. The physical, emotional and psychosocial difficulties posed by herpes infections as well as the degree of debilitation, particularly in immunocompromised patients, are unique for each patient, and the physician should determine therapeutic alternatives based on his or her understanding of the individual patient's needs. Thus Zovirax Capsules are not appropriate in treating all genital herpes infections. The following guidelines may be useful in weighing the benefit/risk considerations in specific disease categories:

First Episodes (primary and nonprimary infections — commonly known as initial genital herpes):

Double-blind, placebo-controlled studies have demonstrated that orally administered Zovirax significantly reduced the duration of acute infection (detection of virus in lesions by tissue culture) and lesion healing. The duration of pain and new lesion formation was decreased in some patient groups. The promptness of initiation of therapy and/or the patient's prior exposure to Herpes simplex virus may influence the degree of benefit from therapy. Patients with mild disease may derive less benefit than those with more severe episodes. In patients with extremely severe episodes, in which prostration, central nervous system involvement, urinary retention or inability to take oral medication require hospitalization and more aggressive management, therapy may be best initiated with intravenous Zovirax.

Recurrent Episodes

Double-blind, placebo-controlled studies in patients with frequent recurrences (6 or more episodes per year) have shown that Zovirax Capsules given for 4 to 6 months prevented or reduced the frequency and/or severity of recurrences in greater than 95% of patients. Clinical recurrences were prevented in 40 to 75% of patients. Some patients experienced increased severity of the first episode following cessation of therapy; the severity of subsequent episodes and the effect on the natural history of the disease are still under study.

The safety and efficacy of orally administered acyclovir in the suppression of frequent episodes of genital herpes have been established only for up to 6 months. Chronic suppressive therapy is most appropriate when, in the judgement of the physician, the benefits of such a regimen outweigh known or potential adverse effects. In general, Zovirax Capsules should not be used for the suppression of recurrent disease in mildly affected patients. Unanswered questions concerning the human relevance of *in vitro* mutagenicity studies and reproductive toxicity studies in animals given very high doses of acyclovir for short periods (see Carcinogenesis, Mutagenesis, Impairment of Fertility) should be borne in mind when designing long-term management for individual patients. Discussion of these issues with patients will provide them the opportunity to weigh the potential for toxicity against the severity of their disease. Thus, this regimen should be considered only for appropriate patients and only for six months until the results of ongoing studies allow a more precise evaluation of the benefit/risk assessment of prolonged therapy.

Limited studies have shown that there are certain patients for whom intermittent short-term treatment of recurrent episodes is effective. This

approach may be more appropriate than a suppressive regimen in patients with infrequent recurrences.

Immunocompromised patients with recurrent herpes infections can be treated with either intermittent or chronic suppressive therapy. Clinically significant resistance, although rare, is more likely to be seen with prolonged or repeated therapy in severely immunocompromised patients with active lesions.

CONTRAINDICATIONS: Zovirax Capsules are contraindicated for patients who develop hypersensitivity or intolerance to the components of the formulation.

WARNINGS: Zovirax Capsules are intended for oral ingestion only.

PRECAUTIONS: General: Zovirax has caused decreased spermatogenesis at high doses in some animals and mutagenesis in some acute studies at high concentrations of drug (see PRECAUTIONS — Carcinogenesis, Mutagenesis, Impairment of Fertility). The recommended dosage and length of treatment should not be exceeded (see DOSAGE AND ADMINISTRATION).

Exposure of Herpes simplex isolates to acyclovir *in vitro* can lead to the emergence of less sensitive viruses. The possibility of the appearance of less sensitive viruses in man must be borne in mind when treating patients. The relationship between the *in vitro* sensitivity of Herpes simplex virus to acyclovir and clinical response to therapy has yet to be established.

Because of the possibility that less sensitive virus may be selected in patients who are receiving acyclovir, all patients should be advised to take particular care to avoid potential transmission of virus if active lesions are present while they are on therapy. In severely immunocompromised patients, the physician should be aware that prolonged or repeated courses of acyclovir may result in selection of resistant viruses which may not fully respond to continued acyclovir therapy.

Drug Interactions: Co-administration of probenecid with intravenous acyclovir has been shown to increase the mean half-life and the area under the concentration-time curve. Urinary excretion and renal clearance were correspondingly reduced.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Acyclovir was tested in lifetime bioassays in rats and mice at single daily doses of 50, 150 and 450 mg/kg given by gavage. There was no statistically significant difference in the incidence of tumors between treated and control animals, nor did acyclovir shorten the latency of tumors. In 2 *in vitro* cell transformation assays, used to provide preliminary assessment of potential oncogenicity in advance of these more definitive life-time bioassays in rodents, conflicting results were obtained. Acyclovir was positive at the highest dose used in one system and the resulting morphologically transformed cells formed tumors when inoculated into immunosuppressed, syngeneic, weanling mice. Acyclovir was negative in another transformation system considered less sensitive.

In acute studies, there was an increase, not statistically significant, in the incidence of chromosomal damage at maximum tolerated parenteral doses of 100 mg/kg acyclovir in rats but not Chinese hamsters; higher doses of 500 and 1000 mg/kg were clastogenic in Chinese hamsters. In addition, no activity was found after 5 days dosing in a dominant lethal study in mice. In 6 of 11 microbial and mammalian cell assays, no evidence of mutagenicity was observed. At 3 loci in a Chinese hamster ovary cell line, the results were inconclusive. In 2 mammalian cell assays (human lymphocytes and L5178Y mouse lymphoma cells *in vitro*), positive responses for mutagenicity and chromosomal damage occurred, but only at concentrations at least 400 times the acyclovir plasma levels achieved in man.

Acyclovir has not been shown to impair fertility or reproduction in mice (450 mg/kg/day, p.o.) or in rats (25 mg/kg/day, s.c.). At 50 mg/kg/day s.c. in the rat, there was a statistically significant increase in post-implantation loss, but no concomitant decrease in litter size. In female rabbits treated subcutaneously with acyclovir subsequent to mating, there was a statistically significant decrease in implantation efficiency but no concomitant decrease in litter size at a dose of 50 mg/kg/day. No effect upon implantation efficiency was observed when the same dose was administered intravenously. In a rat peri- and postnatal study at 50 mg/kg/day s.c., there was a statistically significant decrease in the group mean numbers of corpora lutea, total implantation sites and live fetuses in the F₁ generation. Although not statistically significant,

there was also a dose related decrease in group mean numbers of live fetuses and implantation sites at 12.5 mg/kg/day and 25 mg/kg/day, s.c. The intravenous administration of 100 mg/kg/day, a dose known to cause obstructive nephropathy in rabbits, caused a significant increase in fetal resorptions and a corresponding decrease in litter size. However, at a maximum tolerated intravenous dose of 50 mg/kg/day in rabbits, there were no drug-related reproductive effects.

Intraperitoneal doses of 320 or 80 mg/kg/day acyclovir given to rats for 1 and 6 months, respectively, caused testicular atrophy. Testicular atrophy was persistent through the 4-week post-dose recovery phase after 320 mg/kg/day; some evidence of recovery of sperm production was evident 30 days postdose. Intravenous doses of 100 and 200 mg/kg/day acyclovir given to dogs for 31 days caused aspermatogenesis. Testicles were normal in dogs given 50 mg/kg/day, i.v. for one month.

Pregnancy: Teratogenic Effects: Pregnancy Category C. Acyclovir was not teratogenic in the mouse (450 mg/kg/day, p.o.), rat (50 mg/kg/day, s.c.) or rabbit (50 mg/kg/day, s.c. and i.v.). There are no adequate and well-controlled studies in pregnant women. Acyclovir should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. Although acyclovir was not teratogenic in animal studies, the drug's potential for causing chromosome breaks at high concentration should be taken into consideration in making this determination.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Zovirax is administered to a nursing woman. In nursing mothers, consideration should be given to not using acyclovir treatment or discontinuing breastfeeding.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS — Short-Term Administration: The most frequent adverse reactions reported during clinical trials were nausea and/or vomiting in 8 of 298 patient treatments (2.7%) and headache in 2 of 298 (0.6%). Less frequent adverse reactions, each of which occurred in 1 of 298 patient treatments (0.3%), included diarrhea, dizziness, anorexia, fatigue, edema, skin rash, leg pain, inguinal adenopathy, medication taste and sore throat.

Long-Term Administration: The most frequent adverse reactions reported in studies of daily therapy for 3 to 6 months were headache in 33 of 251 patients (13.1%), diarrhea in 22 of 251 (8.8%), nausea and/or vomiting in 20 of 251 (8.0%), vertigo in 9 of 251 (3.6%), and arthralgia in 9 of 251 (3.6%). Less frequent adverse reactions, each of which occurred in less than 3% of the 251 patients (see number of patients in parentheses), included skin rash (7), insomnia (4), fatigue (7), fever (4), palpitations (1), sore throat (2), superficial thrombophlebitis (1), muscle cramps (2), paronychia (1), menstrual abnormality (4), acne (3), lymphadenopathy (2), irritability (1), accelerated hair loss (1), and depression (1).

DOSAGE AND ADMINISTRATION: Treatment of initial genital herpes: One 200 mg capsule every 4 hours, while awake, for a total of 5 capsules daily for 10 days (total 50 capsules).

Chronic suppressive therapy for recurrent disease: One 200 mg capsule 3 times daily for up to 6 months. Some patients may require more drug, up to one 200 mg capsule 5 times daily for up to 6 months.

Intermittent Therapy: One 200 mg capsule every 4 hours, while awake, for a total of 5 capsules daily for 5 days (total 25 capsules). Therapy should be initiated at the earliest sign or symptom (prodrome) of recurrence.

Patients With Acute or Chronic Renal Impairment: One 200 mg capsule every 12 hours is recommended for patients with creatinine clearance ≤ 10 ml/min/1.73 m².

HOW SUPPLIED: Zovirax Capsules (blue, opaque) containing 200 mg acyclovir and printed with "Wellcome ZOVIRAX 200". Bottles of 100 (NDC-0081-0991-55) and unit dose pack of 100 (NDC-0081-0991-56).

Store at 15°-30°C (59°-86°F) and protect from light.

*In controlled studies, recurrences were totally prevented for 4 to 6 months in up to 75% of patients.



Burroughs Wellcome Co.
Research Triangle Park
North Carolina 27709

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OFFICIAL CALL HOUSE OF DELEGATES

HOUSE OF DELEGATES Meetings Scheduled

Notice to: Delegates, Alternate Delegates, Officials of the North Carolina Medical Society, and Presidents and Secretaries of county medical societies.

Sessions of the HOUSE OF DELEGATES will convene in the Cardinal Ballroom, Pinehurst Hotel, Pinehurst, North Carolina, at the following times:

Thursday, April 30, 1987 — 9:30 a.m. — Opening Session

Saturday, May 2, 1987 — 2:00 p.m. — Second Session

A member of the CREDENTIALS COMMITTEE will be present at the Desk in the West Lobby, Wednesday, April 29, 1987, 3:00 p.m. to 5:00 p.m., and Thursday, April 30, 1987, 8:30 a.m. to 10:00 a.m. to certify Delegates. Delegates are urged to bring their Credential Cards for presentation at the Registration Desk. Delegate Badges must be worn to be seated in the HOUSE OF DELEGATES.

REFERENCE COMMITTEE HEARINGS

Reference Committee hearings are scheduled to begin Thursday, April 30, 1987, at 2:00 p.m.

JOHN W. FOUST, M.D., President
HENRY J. CARR, JR., M.D., President-Elect
T. REGINALD HARRIS, M.D., Speaker
JOHN A. FOGG, M.D., Vice-Speaker
JOHN T. DEES, M.D., Secretary
GEORGE E. MOORE, Executive Vice-President

Letters to the Editor

Congratulations

To the Editor:

As those who've known you as teacher, super-clinician and stimulator would have expected, you have changed the *North Carolina Medical Journal* from a boring, worthless, embarrassingly provincial, "throw-away" magazine into an interesting, highly readable and instructive publication. North Carolina doctors should be proud to see it in any library!

In reference to your Editor's note, page 565, December 1986 (Giannetto LA and Neelon FA, Getting Up Groggy), I was mildly disappointed that you didn't give poor old Elliott Cutler credit for finding and removing Eaton's tumor.

Parenthetically — in my second year of private practice before anyone sent me a stomach or rectum to do, I was referred a 50-year-old Wadesboro woman who had "crazy spells" and severe hypoglycemia. Even though I "cured" her, I never had another insulinoma in 35 subsequent years. Maybe Billy Peete did them all at Duke?

Congratulations and thanks for the new *North Carolina Medical Journal*.

Addison Brenizer, M.D.
Harvard Medical School 1940 &
Massachusetts General Hospital seq.
1333 Queens Rd.
Charlotte 28207

Responses to Dr. Crist's editorial

To the Editor:

It was with great regret that I read the recent editorial in the November issue of *North Carolina Medical Journal*, entitled "Sobering Thoughts" (Crist et al, 1986;47:511). I was indeed "sobered" to read such bigoted trash. What right does the North Carolina Medical Society have to single out any religion with this type of hate propaganda! As a Catholic physician, I am outraged. As a member of the North Carolina Medical Society, I am astonished. I demand an apology from the North Carolina Medical Society and its "official organ," the *North Carolina Medical Journal*.

John P. Stella, M.D.
1502 Darian Dr.
Elizabeth City 27909

To the Editor:

I was very surprised to see this very "left wing" editorial appearing in this journal. Does Dr. Crist make a living off of abortions? Does he make such humanitarian gestures to women who cannot pay? I frown at such ma-

terial appearing in this journal. The article is obviously very opinionated and inflammatory. There are many things that appear in this editorial that I strongly disagree with and hope that other conservative physicians in North Carolina will respond. I am particularly opposed to abortions and feel the physician who makes his living off of abortions can only speak in favor of abortions. I do not see how he can be objective. I hope that you have editorials appearing with viewpoints differing from Dr. Crist and his colleagues. As a new member of the North Carolina Medical Association, I look forward to seeing further response.

Gregory L. Jones, M.D.
Saratoga Medical Clinic
Saratoga 27873

To the Editor:

Everyone has a right to an opinion, even Takey Crist and the Pope. What is fascinating to me is the language that we use in trying to persuade others toward our own opinion and dissuade them away from the opinion of others. I am, in this debate, particularly struck by the use of the code words: "reproductive health care policy" is the code word for abortion; "moral" is the code word for sexually continent.

It is most interesting to see my fellow humans claim either God or reason as the justification for our opinions. Having never been one to shy away from having an opinion of my own, I surely enjoy seeing my colleagues roar in print. We are all so often like the electricity in the incandescent light bulb: eighty percent heat and twenty percent light.

John R. Dykers, Jr., M.D.
P.O. Box 565
Siler City 27344

Dr. Foust's reply to Dr. Joyce

To Dr. Joyce:

I appreciate very much the copy of your letter to Dr. Eugene Stead (1986;48:45), Editor of the *North Carolina Medical Journal*, expressing your displeasure at the article that was listed as an editorial comment in the November 1986 *North Carolina Medical Journal* (Crist et al).

I trust you will get response from the Editorial Board of the *North Carolina Medical Journal* concerning your voiced disapproval and, hopefully, satisfaction can be obtained from that Board. I can assure you that this does not express the philosophy of the North Carolina Medical Society, as you are well aware.

John W. Foust, M.D.
President, North Carolina Medical Society

Bulletin Board

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Continuing Medical Education

Please note: The Continuing Medical Education Programs at Bowman Gray, Duke, East Carolina (ECU) and UNC Schools of Medicine, Dorothea Dix, and Burroughs Wellcome Company are accredited by the American Medical Association. Therefore CME programs sponsored or cosponsored by these schools automatically qualify for AMA Category I credit toward the AMA's Physician Recognition Award, and for North Carolina Medical Society Category A credit. Where AAFP credit has been obtained, this also is indicated.

IN STATE

February 20

Pediatrics Day 1987

Place: Greenville

Fee: \$55

Credit: 6 hours Category I AMA

Info: The Office of CME, ECU School of Medicine, Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

March 5-12

Review of Clinical Chemistry for Practicing Pathologists & Clinical Chemists

Place: Greenville

Fee: \$315

Credit: 40 hours Category I AMA

Info: The Office of CME, ECU School of Medicine, Box 7224, Greenville 27835-7224. 919/758-5200, ext 28

March 11

Family Practice Update '87

Place: Greenville

Fee: \$55

Credit: 7 hours Category I AMA

Info: The Office of CME, ECU School of Medicine, Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

March 21

Eighth Annual Pulmonary Disease Update

Place: Greenville

Fee: \$55

Credit: 6.5 hours Category I AMA

Info: The Office of CME, ECU School of Medicine, Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

March 26-27

Growth Control and Cancer: Molecular Approaches and Clinical Implications

Place: Chapel Hill

Info: Dianne Shaw, Lineberger Cancer Research Center, School of Medicine, University of North Carolina, Chapel Hill 27514. 919/966-3036

April 3

Rehabilitation Medicine: Head Injuries

Place: Greenville

Credit: 7 hours Category I AMA

Info: Office of CME, ECU School of Medicine, P.O. Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

April 3-5

Sixth Annual Ultrasound Symposium

Place: Greensboro

Credit: 16 hours Category I AMA

Info: Sharon Hughes, President, NC Ultrasound Society. 919/748-4505

April 9

North Carolina Clinical Neuro-Ophthalmology Review

Place: Chapel Hill

Info: Baird S. Grimson, M.D., Dept of Ophthalmology, University of North Carolina, 617 Clinical Science Bldg. 229H, Chapel Hill 27514. 919/966-5296

April 10

Plasma Cell Myeloma and Related Diseases

Place: Durham

Credit: 6 hours Category I AMA

Fee: \$75

Info: Myeloma Symposium, Box 3096 DUMC, Durham 27710

April 10-11

Advanced Cardiac Life Support Provider Course

Place: Asheville

Credit: 16 hours Category I AMA

Fee: \$200

Info: Daniel L. Dolan, M.D., MAHEC, 501 Biltmore Ave., Asheville 28801-4686. 704/258-0881

April 11-22

Highway Safety Conference

Place: Boone

Fee: \$25

Credit: 7 Hours Category I AMA

Info: W. Douglas Wooten, Head, Highway Safety Branch, Div. of Health Service, P.O. Box 2091, Raleigh 27602. 919/733-3222

April 22

Neonatal Emergencies: Recognition and Treatment

Place: Greenville

Credit: 6 hours Category I AMA

Fee: \$55

Info: Office of CME, ECU School of Medicine, P.O. Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

April 25

Fifteenth Annual New Bern Symposium: The Care of the Elderly

Place: New Bern

Info: Wm. B. Hunt, Jr., M.D., Symposium Director, P.O. Box 2157, New Bern 28560. 919/633-8608

May 13

Common Diagnostic Problems in Surgical Pathology: A Practical Approach

Place: Greenville

Fee: \$55

Credit: 7 hours Category I AMA

Info: The Office of CME, ECU School of Medicine, P.O. Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

June 15-17

Surgery for Coronary Artery Disease

Place: Durham

Fee: \$460 ACC members; \$525 others

Credit: 17 hours Category I ACCME

Info: Registration Secretary, Extramural Programs Dept, American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 800/253-4636; in MD or AK 301/897-5400

Nursing

Except where otherwise noted, contact Nettie Wilburn, CPS, Office of Continuing Education, University of North Carolina, Chapel Hill 27514 919/966-3638

February 12-13

Communication Skills for the Nurse Manager
Place: Chapel Hill
Credit: 1.32 CEUs
Fee: \$150

February 19-20

Human Response to AIDS — Coping and Caring
Place: Chapel Hill
Credit: 1.32 CEUs
Fee: \$70

February 20-21

Writing and Publishing
Place: Chapel Hill
Credit: 2.04 CEUs
Fee: \$180

May 13-14

The Systematic Process of Instructional Development
Place: Chapel Hill
Credit: 13.2 CEUs pending
Fee: \$110

June 1-9

Summer Institute. Gerontology for Nurse Educators
Place: Chapel Hill
Credit: 3 CEUs
Fee: \$3

OUT OF STATE

February 20-21

Flexible Fiberoptic Sigmoidoscopy
Place: Augusta, GA
Info: Division of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

February 21-28

Duke at Vail: Symposium on Inflammatory Diseases
Place: Vail, CO
Credit: 20 hours Category 1 AMA
Fee: \$350; \$250 Residents and Interns
Info: Angelika Langen, Box 3135 DUMC, Durham 27710. 919/684-2504

February 22-25

Rheumatology at Snowshoe
Place: Snowshoe, WV
Credit: 15 hours Category 1 AMA
Fee: \$225
Info: Office of CME, West Virginia University School of Medicine, G-104 Basic Sciences Bldg., Morgantown, WV 26506. 304/293-3937

February 22-27

Diagnostic Imaging: Update 1987
Place: Park City, UT
Credit: 24.5 hours Category 1 AMA
Fee: \$495
Info: 415/476-5808

February 23-28

6th Annual West Coast Symposium in Doppler Ultrasound
Place: Newport Beach, CA
Credit: 30 hours Category 1 AMA
Info: Lisa Krehbiel, Institute for Medical Studies, 30131 Town Center Dr., Ste 215, Laguna Niguel, CA 92677. 714/495-4499

February 23-28

Symposium in Doppler & 2-D Echocardiography
Place: San Antonio, TX
Fee: \$895
Credit: 40 hours Category 1 AMA
Info: Lisa Krehbiel, 30131 Town Center Dr. #215, Laguna Niguel, CA 92677. 714/495-4499

February 25-28

The Nineteenth Teaching Conference in Clinical Cardiology
Place: Bal Harbour, FL
Fee: \$400; \$375 Fellows & members AHA Council on Clinical Cardiology; \$250 physicians in training
Credit: 28 hours Category 1 AMA; AAFP
Info: Michael S. Gordon, M.D., Ph.D., University of Miami School of Medicine (D-41), P.O. Box 016960, Miami, FL 33101. 305/547-6491

February 26-28

Cardiovascular Surgery
Place: Bethesda, MD
Credit: 18 hours Category 1 AMA
Fee: \$415 ACC members, \$465 non-members
Info: Program Registrar, Heart House Learning Center, American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814, 301/897-5400, ext 241, or 800/253-INFO

February 27-28

Advance Trauma Life Support
Place: Mountain Home, TN
Info: Ramona Miller, Ph.D., Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

March 1-7

Update '87: Office Obstetrics and Gynecology
Place: Park City, UT
Info: Charlene E. Lee, Scott & White Memorial Hospital, 2401 South 31st St., Temple, TX 76508. 817/774-4073

March 2-7 (and April 27-May 2)

22nd Annual Family Practice Symposium
Place: Augusta, GA
Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

March 4-8

Pan American Allergy Society Annual Training Course & Seminar
Place: San Antonio, TX
Fee: \$415 members
Info: Betty Kahler, PAAS, 229 Parking Way, Lake Jackson, TX 77566. 409/297-8964 or 297-4069

March 6-7

Cardiology Department Management Conference
Place: New Orleans, LA
Credit: 10 hours Category 1 AMA
Fee: \$350 approx.
Info: Lisa Krehbiel, Institute for Medical Studies, 30131 Town Center Dr. Ste. 215, Laguna Niguel, CA 92677. 714/495-4499

March 7-8

Breast Imaging Update
Place: San Francisco, CA
Credit: 13 hours Category 1 AMA
Fee: \$295
Info: 415/476-5808

March 8-13

Annual Meeting, US-Canadian Division of the International Academy of Pathology
Place: Chicago, IL
Info: Nathan Kuafman, M.D., Secretary-Treasurer, US-Canadian Division, International Academy of Pathology, Bldg. C, Ste. B, 3515 Wheeler Rd., Augusta, GA 30909. 404/733-7550

March 9-13

Hawaii '87: Critical Issues in Primary Care
Place: Kauai, HA
Credit: 20 hours Category 1 AMA, AAFP
Info: The Pacific Institute of CME, P.O. Box 1059, Koloa, Kauai, HA 96756. 808/742-7471

March 9-13

Diagnostic Radiology
Place: San Francisco, CA
Credit: 34 hours Category 1 AMA
Fee: \$495
Info: 415/476-5808

March 14-15

Contemporary Trends in Diagnostic Nuclear Medicine

Place: San Francisco, CA

Fee: \$352

Info: 415/476-5808

March 16-20

Diagnostic Imaging 1987

Place: Kauai, HI

Credit: 24 hours Category 1 AMA

Fee: \$495

Info: 415/476-5808

March 19-20

Hospital Infections in 1987 and Beyond: New Issues, Problems and Strategies

Place: Hilton Head Island, SC

Credit: 9 hours Category 1 AMA, CEUs

Info: Loraine E. Price, B.S.N., C.I.C., Div. of Infectious Diseases, UNC School of Medicine, 547 Clinical Sciences Bldg. 229H, Chapel Hill 27514. 919/966-3242

March 29-April 1

Cardiology Update

Place: Phoenix, AZ

Credit: 26 hours Category 1 AMA

Fee: \$395 approx.

Info: Lisa Krehbiel, Institute for Medical Studies, 30131 Town Center Dr. Ste 215, Laguna Niguel, CA 92677. 714/495-4499

April 2

School Health

Place: Johnson City, TN

Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

April 3-5

Ophthalmologic Plastic Surgery, Orbital Disease, and Neuro-Ophthalmology

Place: Williamsburg, VA

Fee: \$315

Info: Kay Parrott, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 9-10

16th Annual School Health Education

Place: Johnson City, TN

Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

April 9-11

Thoracic Imaging Update

Place: Monterey, CA

Credit: 13 hours Category 1 AMA

Fee: \$295

Info: 415/476-5808

April 9-11

Current Concepts in Vascular Surgery

Place: Philadelphia, PA

Info: Fay Zelle, Hahnemann University, Broad and Vine Streets, M.X. 623, Philadelphia, PA 19102. 215/448-8263

April 10-12

OB/GYN and Abdominal Sonography: Update '87

Place: San Francisco, CA

Credit: 14.5 hours Category 1 AMA

Fee: \$325

Info: 415/476-5808

April 10-12

5th Annual MCV Symposium: New Trends in Anesthesia

Place: Williamsburg, VA

Fee: \$275

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 10-12

22nd Annual Pediatric Springfest

Place: Williamsburg, VA

Fee: \$250

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 23-25

Cardiology

Place: Johnson City, TN

Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

April 23-25

23rd Annual Postgraduate Course in Radiology: The Chest

Place: Richmond, VA

Fee: \$325

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 24-25

The Terminally Ill Patient: Psychological, Social, Legal, and Ethical Issues

Place: Boston, MA

Info: Harvard Medical School, Dept. of CME, Boston, MA 02115. 617/732-1525

April 24-26

9th Annual Conference on Emergency Medicine for the Primary Care Physician

Place: Williamsburg, VA

Fee: \$295

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 24-26

7th Annual Clinical Concerns in Primary Care: Office Cardiology

Place: Williamsburg, VA

Fee: \$295

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 27-May 2 (and March 2-7)

22nd Annual Family Practice Symposium

Place: Augusta, GA

Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

May 2-9

Doppler and 2-D Echocardiology

Place: Newport Beach, CA

Fee: \$895 approx.

Credit: 40 hours Category 1 AMA

Info: Lisa Krehbiel, Institute for Medical Studies, 30131 Town Center Dr., Ste. 215, Laguna Niguel, CA 92677. 714/495-4499

May 8-10

6th Annual MCV Cardiology Conference

Place: Williamsburg, VA

Fee: \$325

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

May 14-16

Vascular Surgery 1987: Third International Vascular Symposium

Place: New York, NY

Fee: \$400

Credit: 24 hours Category 1 AMA

Info: Ann J. Boehme, Assoc. Director for CME, Long Island Jewish Medical Center, New Hyde Park, NY 11042. 718/470-8650

May 18-19

14th Annual Hans Berger Day and EEG Symposium

Place: Richmond, VA

Fee: \$250

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

May 19-22

Cell Calcium Metabolism '87: Physiology, Biochemistry, Pharmacology, and Clinical Implications
Place: Washington, D.C.
Info: Dr. Gary Fiskum, Dept. of Biochemistry, The George Washington University of Medicine and Health Sciences, 2300 Eye St. NW, Washington, D.C. 20037.

May 23-25

Gynecologic Urology and Pelvic Surgery
Place: Williamsburg, VA
Fee: \$260
Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

May 26-30

Fifth Annual Cardiology Update
Place: Honolulu, HA
Fee: \$395
Info: Lisa Krehbiel, 30131 Town Center Dr., Ste. 215, Laguna Niguel, CA 92677. 714/495-4499

May 30

Tough Psychiatry Problems in Medical Practice
Place: Gatlinburg, TN
Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

June 3-7

Eleventh Annual Postgraduate Course on Rehabilitation of the Brain-Injured Adult and Child
Place: Williamsburg, VA
Fee: \$285
Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Station, Richmond, VA 23298-0001. 804/786-0494

June 11-13

Current Advances in Pediatric Practice
Place: Gatlinburg, TN
Credit: 12 hours Category I/PREP, AAP, AAFP
Info: Dr. Sandra Loucks, University of Tennessee Memorial Research Center and Hospital, Dept. of Pediatrics, 1924 Alcoa Highway, Knoxville, TN 37920. 615/544-9331

June 15-18

18th Annual Internal Medicine Symposium
Place: Kiawah Island, SC
Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

Our warehouses here at the Government Printing Office contain more than 16,000 different Government publications. Now we've put together a catalog of nearly 1,000 of the most popular books in our inventory. Books like *Infant Care*, *National Park Guide and Map*, *The Space Shuttle at Work*, *Federal Benefits for Veterans and Dependents*, *Merchandising Your Job Talents*,

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Before prescribing, see complete prescribing information in SK&F CD literature or PDR. The following is a brief summary.

*** WARNING**

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically serum K^+ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K^+ intake. Associated widened QRS complex or arrhythmia requires prompt additional therapy. Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If then use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: The bioavailability of the hydrochlorothiazide component of 'Dyazide' is about 50% of the bioavailability of the single entity. Theoretically, a patient transferred from the single entities of triamterene and hydrochlorothiazide may show an increase in blood pressure or fluid retention. Similarly, it is also possible that the lesser hydrochlorothiazide bioavailability could lead to increased serum potassium levels. However, extensive clinical experience with 'Dyazide' suggests that these conditions have not been commonly observed in clinical practice. Angiotensin-converting enzyme (ACE) inhibitors can elevate serum potassium, use with caution with 'Dyazide'. Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with atropine, B or corticosteroids or corticotropin (ACTH)). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide, dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in carinotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function. Thiazides may add to or potentiate the action of other anti-hypertensive drugs. Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth, anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions, nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances, postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

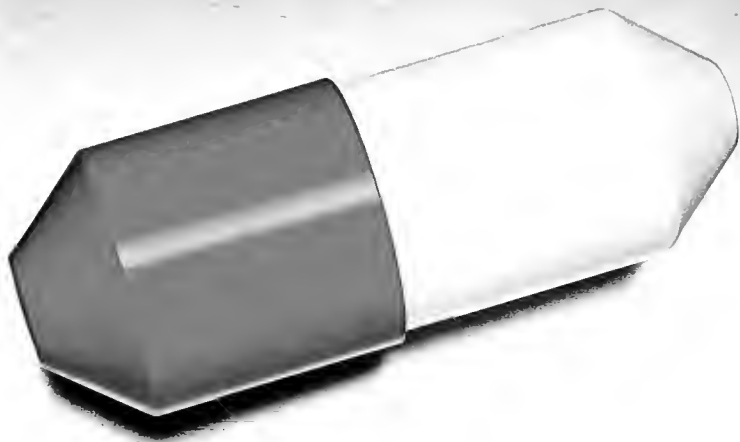
Supplied: 'Dyazide' is supplied as a red and white capsule, in bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak™ unit-of-use bottles of 100.

BRS-DZ L42

In Hypertension*... When You Need to Conserve K^+

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Serum K^+ and BUN should be checked periodically (see Warnings and Precautions).



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**There's never been
a better time for her...
and
PREMARIN[®]**
(Conjugated Estrogens Tablets)

Now the evidence looks better than ever

Significantly reduced risk of endometrial hyperplasia

Endometrial hyperplasia was significantly reduced when progestin was added to PREMARIN therapy for more than ten days a month.¹⁻⁴ The risk of endometrial hyperplasia may also be reduced through cyclic administration of unopposed, low-dose PREMARIN.

Effect on lipids—an important feature

PREMARIN used alone does not adversely affect lipid levels. In fact, a clinical study has shown a significant increase in HDL cholesterol—from 49.7 mg/dL to 56.4 mg/dL—and decrease in LDL cholesterol—from 165.1 mg/dL to 138.1 mg/dL—after one year of therapy with PREMARIN, 0.625 mg.⁵

Low-dose control of menopausal symptoms*

PREMARIN effectively relieves vasomotor symptoms, such as hot flashes. When estrogen deficiency is limited to atrophic vaginitis, PREMARIN[®] (conjugated estrogens) Vaginal Cream restores the vaginal environment to its premenopausal state.

The most widely used, most extensively studied estrogen worldwide.

PREMARIN[®]
(Conjugated Estrogens Tablets)

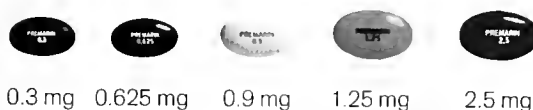
Most trusted for more reasons

*PREMARIN is indicated for moderate-to-severe vasomotor symptoms.

Please see following page for brief summary of prescribing information.

For moderate-to-severe
vasomotor symptoms

PREMARIN® (Conjugated Estrogens Tablets)



The appearance of these tablets is a trademark of Ayerst Laboratories

For atrophic vaginitis

PREMARIN® (Conjugated Estrogens)

Vaginal
Cream

0.625mg/g



BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION AND PATIENT INFORMATION, SEE PACKAGE CIRCULARS)

PREMARIN® Brand of conjugated estrogens tablets, USP

PREMARIN® Brand of conjugated estrogens Vaginal Cream in a nonliquefying base

1. ESTROGENS HAVE BEEN REPORTED TO INCREASE THE RISK OF ENDOMETRIAL CARCINOMA

Three independent case control studies have reported an increased risk of endometrial cancer in postmenopausal women exposed to exogenous estrogens for more than one year. This risk was independent of the other known risk factors for endometrial cancer. These studies are further supported by the finding that incidence rates of endometrial cancer have increased sharply since 1969 in eight different areas of the United States with population-based cancer reporting systems, an increase which may be related to the rapidly expanding use of estrogens during the last decade. The three case control studies reported that the risk of endometrial cancer in estrogen users was about 4.5 to 13.9 times greater than in nonusers. The risk appears to depend on both duration of treatment and on estrogen dose. In view of these findings, when estrogens are used for the treatment of menopausal symptoms, the lowest dose that will control symptoms should be utilized and medication should be discontinued as soon as possible. When prolonged treatment is medically indicated, the patient should be reassessed on at least a semiannual basis to determine the need for continued therapy. Although the evidence must be considered preliminary, one study suggests that cyclic administration of low doses of estrogen may carry less risk than continuous administration, it therefore appears prudent to utilize such a regimen. Close clinical surveillance of all women taking estrogens is important. In all cases of undiagnosed persistent or recurring abnormal vaginal bleeding adequate diagnostic measures should be undertaken to rule out malignancy. There is no evidence at present that "natural" estrogens are more or less hazardous than "synthetic" estrogens at equieffective doses.

2. ESTROGENS SHOULD NOT BE USED DURING PREGNANCY

The use of female sex hormones, both estrogens and progestogens, during early pregnancy may seriously damage the offspring. It has been shown that females exposed in utero to diethylstilbestrol, a non-steroidal estrogen, have an increased risk of developing in later life a form of vaginal or cervical cancer that is ordinarily extremely rare. This risk has been estimated as not greater than 4 per 1,000 exposures. Furthermore, a high percentage of such exposed women (from 30% to 90%) have been found to have vaginal adenosis, epithelial changes of the vagina and cervix. Although these changes are histologically benign, it is not known whether they are precursors of malignancy. Although similar data are not available with the use of other estrogens, it cannot be presumed they would not induce similar changes. Several reports suggest an association between intrauterine exposure to female sex hormones and congenital anomalies including congenital heart defects and limb reduction defects. One case control study estimated a 4.7-fold increased risk of limb reduction defects in infants exposed in utero to sex hormones (oral contraceptives, hormone withdrawal tests for pregnancy, or attempted treatment for threatened abortion). Some of these exposures were very short and involved only a few days of treatment. The data suggest that the risk of limb reduction defects in exposed fetuses is somewhat less than 1 per 1,000. In the past, female sex hormones have been used during pregnancy in an attempt to treat threatened or habitual abortion. There is considerable evidence that estrogens are ineffective for these indications, and there is no evidence from well controlled studies that progestogens are effective for these uses. If PREMARIN is used during pregnancy or if the patient becomes pregnant while taking this drug, she should be apprised of the potential risks to the fetus, and the advisability of pregnancy continuation.

DESCRIPTION: PREMARIN (conjugated estrogens, USP) contains a mixture of estrogens, obtained exclusively from natural sources, blended to represent the average composition of material derived from pregnant mares urine, containing estrone, estradiol, and 17 α -hydroxyestrone, together with smaller amounts of 17 β -estradiol, equilin, and 17 α -dihydroequilenin as salts of their sulfate esters. Tablets are available in 0.3 mg, 0.625 mg, 0.9 mg, 1.25 mg, and 2.5 mg strengths of conjugated estrogens. Cream is available as 0.625 mg conjugated estrogens per gram.

INDICATIONS AND USAGE: PREMARIN (conjugated estrogens tablets, USP) Moderate-to-severe vasomotor symptoms associated with the menopause. (There is no evidence that estrogens are effective for nervous symptoms or depression without associated vasomotor symptoms and they should not be used to treat such conditions.) Osteoporosis (abnormally low bone mass). Atrophic vaginitis. Kraurosis vulvae. Female castration.

PREMARIN (Conjugated Estrogens) Vaginal Cream is indicated in the treatment of atrophic vaginitis and kraurosis vulvae. PREMARIN HAS NOT BEEN SHOWN TO BE EFFECTIVE FOR ANY PURPOSE DURING PREGNANCY AND ITS USE MAY CAUSE SEVERE HARM TO THE FETUS (SEE BOXED WARNING).

Concomitant Progestin Use: The lowest effective dose appropriate for the specific indication should be utilized. Studies of the addition of a progestin for 7 or more days of a cycle of estrogen administration have reported a lowered incidence of endometrial hyperplasia. Morphological and biochemical studies of the endometrium suggest that 10 to 13 days of progestin are needed to provide maximal maturation of the endometrium to eliminate any hyperplastic changes. Whether this will provide protection from endometrial carcinoma has not been clearly established. There are possible additional risks which may be associated with the inclusion of progestin in estrogen replacement regimens. (See PRECAUTIONS.) The choice of progestin and dosage may be important; product labeling should be reviewed to minimize possible adverse effects.

CONTRAINDICATIONS: Estrogens should not be used in women (or men) with any of the following conditions: 1 Known or suspected pregnancy, or a history of an appropriately selected patient being treated for metastatic cancer of the breast, or a history of endometrial cancer. 2 Known or suspected estrogen-dependent neoplasia. 3 Known or suspected pregnancy. 4 Undiagnosed abnormal genital bleeding. 5 Active thrombophlebitis or thromboembolic disorders. 6 A past history of thrombophlebitis, thrombosis, or thromboembolic disorders associated with previous estrogen use (except when used in treatment of breast or prostatic malignancy).

WARNINGS: Long-term continuous administration of natural and synthetic estrogens in certain animal species increases the frequency of carcinomas of the breast, cervix, vagina, and liver. There are now reports that estrogens increase the risk of carcinoma of the endometrium in humans. (See Boxed Warning.) At the present time there is no satisfactory evidence that estrogens given to postmenopausal women increase the risk of cancer of the breast, although a recent study has raised this possibility. There is a need for caution in prescribing estrogens for women with a strong family history of breast cancer or who have breast nodules, fibrocystic disease, or abnormal mammograms. A recent study has reported a 2- to 3-fold increase in the risk of surgically confirmed gallbladder disease in women receiving postmenopausal estrogens.

Adverse effects of oral contraceptives may be expected at the larger doses of estrogen used to treat prostatic or breast cancer or postpartum breast engorgement. It has been shown that there is an increased risk of thrombosis in men receiving estrogens for prostatic cancer and women for postpartum breast engorgement. Users of oral contraceptives have an increased risk of diseases, such as thrombophlebitis, pulmonary embolism, stroke, and myocardial infarction. Cases of retinal thrombosis, mesenteric thrombosis, and optic neuritis have been reported in oral contraceptive users. An increased risk of postsurgery thromboembolic complications has also been reported in users of oral contraceptives. If feasible, estrogen should be discontinued at least 4 weeks before surgery of the type associated with an increased risk of thromboembolism, or during periods of prolonged immobilization. Estrogens should not be used in persons with active thrombophlebitis, thromboembolic disorders, or in persons with a history of such disorders in association with estrogen use. They should be used with

caution in patients with cerebral vascular or coronary artery disease. Large doses (5 mg conjugated estrogens per day), comparable to those used to treat cancer of the prostate and breast, have been shown to increase the risk of nonfatal myocardial infarction, pulmonary embolism and thrombophlebitis. When doses of this size are used, any of the thromboembolic and thrombotic adverse effects should be considered a clear risk.

Benign hepatic adenomas should be considered in estrogen users having abdominal pain and tenderness, abdominal mass, or hypovolemic shock. Hepatocellular carcinoma has been reported in women taking estrogen-containing oral contraceptives. Increased blood pressure may occur with use of estrogens in the menopause and blood pressure should be monitored with estrogen use. A worsening of glucose tolerance has been observed in patients on estrogen-containing oral contraceptives. For this reason, diabetic patients should be carefully followed.

PRECAUTIONS: Physicians should obtain a complete medical and family history should be taken prior to the initiation of any estrogen therapy with special reference to blood pressure, breasts, abdomen, and pelvic organs, and should include a Papaniacolaou smear. As a general rule, estrogen should not be prescribed for longer than one year without another physical examination being performed. Conditions influenced by fluid retention such as asthma, epilepsy, migraine, and cardiac or renal dysfunction, require careful observation. Certain patients may develop manifestations of excessive estrogenic stimulation, such as abnormal or excessive uterine bleeding, mastodynia, etc. Prolonged administration of unopposed estrogen therapy has been reported to increase the risk of endometrial hyperplasia in some patients. Oral contraceptives appear to be associated with an increased incidence of mental depression. Patients with a history of depression should be carefully observed. Precocious uterine leiomyomata may increase in size during estrogen use. The pathologist should be advised of estrogen therapy when relevant specimens are submitted. If jaundice develops in any patient receiving estrogen, the medication should be discontinued while the cause is investigated. Estrogens should be used with care in patients with impaired liver function, renal insufficiency, metabolic bone diseases associated with hypercalcemia, or in young patients in whom bone growth is not complete. If concomitant progestin therapy is used, potential risks may include adverse effects on carbohydrate and lipid metabolism.

The following changes may be expected with larger doses of estrogen:

- Increased sulfolobomorphthalen retention
- Increased prothrombin and factors VII, VIII, IX, and X, decreased antithrombin 3, increased non-epinephrine-induced platelet aggregability
- Increased thyroid binding globulin (TBG) leading to increased circulating total thyroid hormone, as measured by PBI, T4 by column, or T4 by radioimmunoassay. Free T3 resin uptake is decreased, reflecting the elevated TBG; free T4 concentration is unaltered
- Impaired glucose tolerance
- Decreased pregnandiol excretion
- Reduced response to metyrapone test
- Reduced serum folate concentration
- Increased serum triglyceride and phospholipid concentration

As a general principle, the administration of any drug to nursing mothers should be done only when clearly necessary since many drugs are excreted in human milk.

ADVERSE REACTIONS: The following have been reported with estrogenic therapy, including oral contraceptives: breakthrough bleeding, spotting, change in menstrual flow, dysmenorrhea, premenstrual-like syndrome, amenorrhea during and after treatment, increase in size of uterine fibromyoma, vaginal candidiasis, change in cervical erosion and in degree of cervical secretion, cystitis-like syndrome, tenderness, enlargement, secretion (of breasts), nausea, vomiting, abdominal cramps, bloating, cholestatic jaundice, chloasma or melasma which may persist when drug is discontinued, erythema multiforme, erythema nodosum, hemorrhagic eruption, loss of scalp hair, hirsutism, sleeping of corneal curvature, intolerance to contact lenses, headache, migraine, dizziness, mental depression, chorea, increase or decrease in weight, reduced carbohydrate tolerance, aggravation of porphyria, edema, changes in libido.

ACUTE OVERDOSEAGE: May cause nausea, and withdrawal bleeding may occur in females.

DOSEAGE AND ADMINISTRATION

PREMARIN® Brand of conjugated estrogens tablets, USP

1 Given cyclically for short-term use only. For treatment of moderate to severe vasomotor symptoms, atrophic vaginitis, or kraurosis vulvae associated with the menopause (0.3 to 2.5 mg or more daily). The lowest dose that will control symptoms should be chosen and medication should be discontinued as promptly as possible. Administration should be cyclic (eg, three weeks on and one week off). Attempts to discontinue or taper medication should be made at three- to six-month intervals.

2 Given cyclically. Female castration. Osteoporosis. Female castration—1.25 mg daily, cyclically. Adjust upward or downward according to response of the patient. For maintenance, adjust dosage to lowest level that will provide effective control. Osteoporosis—0.625 mg daily. Administration should be cyclic (eg, three weeks on and one week off).

Patients with an intact uterus should be monitored for signs of endometrial cancer and appropriate measures taken to rule out malignancy in the event of persistent or recurring abnormal vaginal bleeding.

PREMARIN® Brand of conjugated estrogens Vaginal Cream

Given cyclically for short-term use only. For treatment of atrophic vaginitis or kraurosis vulvae.

The lowest dose that will control symptoms should be chosen and medication should be discontinued as promptly as possible.

Administration should be cyclic (eg, three weeks on and one week off).

Attempts to discontinue or taper medication should be made at three- to six-month intervals.

Usual dosage range: 2 to 4 g daily, intravaginally, depending on the severity of the condition.

Treated patients with an intact uterus should be monitored closely for signs of endometrial cancer and appropriate diagnostic measures should be taken to rule out malignancy in the event of persistent or recurring abnormal vaginal bleeding.

References:

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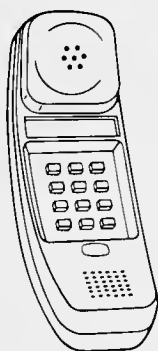
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Index to Advertisers

Ayerst	60a-d, 104b-d	Medical Mutual Insurance Company of N.C.	94
B & B X-Ray, Inc.	108	Medical Protective Company	63
Burroughs Wellcome Co.	58, 96a, b, 97	National Staffing Services Corp.	57
Campbell Laboratories, Inc.	76	NCNB	71
Crumpton Company	Cover 2	Roche Laboratories	72, 73, 93, Cover 3, 4
Hinrichs Financial Group	60	St. Albans	88
Eli Lilly & Company	68b	Smith Kline & French Laboratories	104a
Marion Laboratories, Inc.	76a, b	The Upjohn Company	68a
Medic Computer Systems	105	Winchester Surgical Supply Co.	68

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WARNING: Bumex (bumetanide/Roche) is a potent diuretic which, if given in excessive amounts, can lead to a profound diuresis with water and electrolyte depletion. Therefore, careful medical supervision is required, and dose and dosage schedule have to be adjusted to the individual patient's needs. (See under **DOSE AND ADMINISTRATION** in complete product information.)

INDICATIONS AND USAGE: Edema associated with congestive heart failure, hepatic and renal disease, including the nephrotic syndrome.

Almost equal diuretic response occurs after oral and parenteral administration of Bumex. If impaired gastrointestinal absorption is suspected or oral administration is not practical, Bumex should be given by the intramuscular or intravenous route.

Successful treatment with Bumex following instances of allergic reactions to furosemide suggests a lack of cross-sensitivity.

CONTRAINDICATIONS: Anuria. Hypersensitivity and in patients in hepatic coma or in states of severe electrolyte depletion. Although Bumex can be used to induce diuresis in renal insufficiency, any marked increase in blood urea nitrogen or creatinine, or the development of oliguria during therapy of patients with progressive renal disease, is an indication for discontinuation of treatment.

WARNINGS: Dose should be adjusted to patient's needs. Excessive doses or too frequent administration can lead to profound water loss, electrolyte depletion, dehydration, reduction in blood volume and circulatory collapse with the possibility of vascular thrombosis and embolism, particularly in elderly patients.

Prevention of hypokalemia requires particular attention in patients receiving digitalis and diuretics for congestive heart failure, hepatic cirrhosis and ascites, states of aldosterone excess with normal renal function, potassium-losing nephropathy, certain diarrheal states, or other states where hypokalemia is thought to represent particular added risks to the patients.

In patients with hepatic cirrhosis and ascites, sudden alterations of electrolyte balance may precipitate hepatic encephalopathy and coma. Treatment in such patients is best initiated in the hospital with small doses and careful monitoring of the patient's clinical status and electrolyte balance. Supplemental potassium and/or spironolactone may prevent hypokalemic and metabolic alkalosis in these patients.

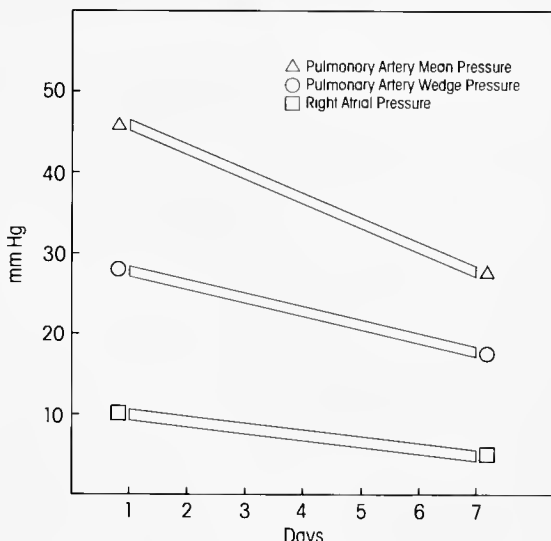
In cats, dogs and guinea pigs, Bumex has been shown to produce atoxicity. Since Bumex is about 40 to 60 times as potent as furosemide, it is anticipated that blood levels necessary to produce atoxicity will rarely be achieved. The potential for atoxicity increases with intravenous therapy, especially of high doses.

Patients allergic to sulfonamides may show hypersensitivity to Bumex.

PRECAUTIONS: Measure serum potassium periodically and add potassium supplements or potassium-sparing diuretics, if necessary. Periodic determinations of other electrolytes are advised in patients treated with high doses or for prolonged periods, particularly in those on low salt diets. Hypernatremia may occur. Reversible elevations of the BUN and creatinine may occur, especially with dehydration and in patients with renal insufficiency. Bumex may increase urinary calcium excretion.

Possibility of effect on glucose metabolism exists. Periodic determinations of blood sugar should be done, particularly in patients with diabetes or suspected latent diabetes.

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Ten patients with CHF showed marked hemodynamic improvement after seven days of BUMEX[®] (bumetanide/Roche) (mean values \pm SE). Adapted from Olesen, *et al.*¹

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Patients should be observed regularly for possible occurrence of blood dyscrasias, liver damage or idiosyncratic reactions.

Especially in presence of impaired renal function, use of parenterally administered Bumex should be avoided in patients to whom aminoglycoside antibiotics are also being given, except in life-threatening conditions.

Drugs with nephrotoxic potential and bumetanide should not be administered simultaneously. Since lithium reduces renal clearance and adds a high risk of lithium toxicity, it should not be given with diuretics.

Probencid should not be administered concurrently with Bumex. Concurrent therapy with indomethacin not recommended.

Bumex may potentiate the effects of antihypertensive drugs, necessitating reduction in dosage.

Interaction studies in humans have shown no effect on digoxin blood levels.

Interaction studies in humans have shown Bumex to have no effect on warfarin metabolism or on plasma prothrombin activity.

Pregnancy: Bumex should be given to a pregnant woman only if the potential benefit justifies the potential risk to the fetus.

Bumetanide may be excreted in breast milk.

Pediatric Use: Safety and effectiveness below age 18 not established.

ADVERSE REACTIONS: Muscle cramps, dizziness, hypotension, headache and nausea, and encephalopathy (in patients with preexisting liver disease).

Less frequent clinical adverse reactions are weakness, impaired hearing, rash, pruritus, hives, electrocardiogram changes, abdominal pain, arthritic pain, musculoskeletal pain and vomiting. Other clinical adverse reactions are vertigo, chest pain, ear discomfort, fatigue, dehydration, sweating, hyperventilation, dry mouth, upset stomach, renal failure, asterixis, itching, nipple tenderness, diarrhea, premature ejaculation and difficulty maintaining an erection.

Laboratory abnormalities reported are hypernatremia, azotemia, hyperglycemia, increased serum creatinine, hypochloremia, hypokalemia, hyponatremia, and variations in CO_2 content, bicarbonate, phosphorus and calcium. Although manifestations of the pharmacologic action of Bumex, these conditions may become more pronounced by intensive therapy.

Diuresis induced by Bumex may also rarely be accompanied by changes in LCH, total serum bilirubin, serum proteins, SGOT, SGPT, alkaline phosphatase, cholesterol, creatinine clearance, deviations in hemoglobin, prothrombin time, hematocrit, platelet counts and differential counts. Increases in urinary glucose and urinary protein have also been seen.

DOSE AND ADMINISTRATION:

Oral Administration: The usual total daily dosage is 0.5 to 2.0 mg and in most patients is given as a single dose.

Parenteral Administration: Administer to patients (IV or IM) with GI absorption problem or who cannot take oral. The usual initial dose is 0.5 to 1 mg given over 1 to 2 minutes. If insufficient response, a second or third dose may be given at 2 to 3 hour intervals up to a maximum of 10 mg a day.

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March 1987
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North Carolina Medical Journal

For Doctors and their Patients

**A Boy (a Bleeder)
and a Bloody
Revolution**

E. Wayne Massey, M.D.
Janice Massey, M.D.

**Duke University
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Wilburt C. Davison, M.D.

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William B. Blythe, M.D.

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Contents

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NCMJ / March 1987, Volume 48, Number 3

EDITORIAL

- 113 Use of Automatic External Defibrillators — An Issue for North Carolina's EMS System
H. Lawson Huggins, Jr., and Roy W. Graves

SCIENTIFIC ARTICLES

- 117 Outpatient Microsurgical Management of Ruptured Lumbar Discs *Larry A. Rogers*
127 A Review of the Basics of Closed Thoracic Drainage *J. Steve Julian and Timothy C. Pennell*

WHAT NC's MDs ARE THINKING

- 133 A Boy (a Bleeder) and a Bloody Revolution *E. Wayne Massey and Janice Massey*

FOR PATIENTS

- 137 The Duke University School of Medicine *Wilburt C. Davison (1927)*
140 Comment *William G. Anyan*
141 Comment *James F. Gifford, Jr.*
142 Comment *Stuart Bondurant*
143 Poetry *Billy F. Andrews*

SOCIOECONOMICS

- 148 Recent Changes in Physician-Hospital CEO Relationships *Thomas P. Weil*

TOXIC ENCOUNTERS

- 152 My Kingdom for a Fix — (T's and Blues) — Was and Is *Ronald B. Mack*

LEARNING EXPERIENCES FROM UNC

- 155 Diuretic-Induced Edema *William B. Blythe*

PHARMACOTHERAPY

- 157 Digibind® — A New Frontier in the Treatment of Digitalis Toxicity *Brad Stolshek*

LEARNING FROM A PATIENT

- 160 An Elderly Patient and a Geriatric Educator *Noel David List*

BULLETIN BOARD

- | | | | |
|-----|------------------------------------|-----|---------------------------|
| 162 | Continuing Medical Education | 116 | Instructions to Authors |
| 165 | Letters to the Editor | 171 | Classified Advertisements |
| 146 | Official Call — House of Delegates | 172 | Index to Advertisers |

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Use of Automatic External Defibrillators — An Issue for North Carolina's EMS System

H. Lawson Huggins, Jr., M.D., and Roy W. Graves, M.D.

The use of automatic external defibrillators by emergency medical technicians would mean earlier defibrillation and lives saved.

Given that defibrillation is the definitive treatment of ventricular fibrillation, it is not surprising that the earliest possible defibrillation is associated with higher success rates of returning to a stable perfusing rhythm. This has been well documented.¹⁻⁶ Now, through the development of automatic external defibrillators (AEDs), the technology exists to allow Emergency Medical Technicians (EMTs) to provide safe earlier defibrillation.

The concept of EMT-defibrillation is endorsed by the American Heart Association, the American College of Emergency Physicians, the Advanced Coronary Treatment Foundation, and the 1985 National Conference on Standards and Guidelines for Cardiopulmonary Resuscitation.^{2,6,7} Presently, a statewide EMS task force is investigating the feasibility of EMT-defibrillation programs. In addition to considering the programs themselves, the task force must decide among manual, semiautomatic, or fully automated defibrillators.

AED Equipment

There are several AEDs now available that are basically variations of the same theme. Most list for approximately \$5000-6000, are portable, and weigh 25-30 lbs. They are powered by rechargeable lead-acid batteries and employ two self-adhesive pads, each with an ECG electrode that is placed over the apex of the heart and the right sternal border. The Heart-Aid 95 (Cardiac Resuscitator Corporation, Portland, OR) is a typical AED device with the added feature of

external pacing for those cases where the patient is in asystole or severe bradycardia.

Through built-in digital software, AEDs analyze multiple parameters (amplitude, frequency, morphology, etc.) of the ECG signal with rhythm algorithms. Also incorporated is an impedance measurement between the two surface electrodes to ensure adequate contact and special filters to identify electrical artifacts.

Once cardiac arrest without pulse or respiration is identified, the two electrodes are placed on the patient's chest. With the Heart-Aid 97, the cardiac rhythm is assessed immediately, and the device can automatically deliver the first defibrillation in as little as 12 seconds if needed. Real-time display is provided by an ECG screen. The ECG strip chart recorder provides an on-site record of the patient's cardiac rhythm for permanent documentation.

Audible voice instructions guide the rescuer through the appropriate steps in treating the victim. Perhaps most important for medical control, the entire resuscitation is recorded on a dual channel recorder. All ECG information as well as voice and background sounds are recorded to provide a reconstruction of the procedure for subsequent medical review.

Clinical Experience with EMT Defibrillation

The effectiveness of early defibrillation in the field has been confirmed in several controlled studies.⁸⁻¹⁰ Stults et al prospectively studied the survival following out-of-hospital cardiac arrests that had been served by two groups of basic ambulance personnel.⁸ The first group was trained to recognize and defibrillate ventricular fibrillation. Twelve pa-

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tients of 64 (19%) who were found in ventricular fibrillation were resuscitated and discharged alive from the hospital. The second group served as a control where early defibrillation was not attempted and only basic life support was employed. One of 31 of these patients was discharged alive from the hospital ($P < 0.05$).

Similarly, Eisenberg et al³ found that patients discharged alive from the hospital represented 26% of 36 victims treated with early defibrillation by EMTs (who had had a ten-hour training course to recognize ventricular fibrillation and use a manual defibrillator), and just 7% of 56 control group victims treated with only basic life support by EMTs.

Automatic versus Manual Defibrillation

Clinical trials of the automatic versus manual defibrillator come most notably from Iowa and King County, Washington. Cummins et al¹¹ studied the performance of the EAD used by paramedics on 39 people with out-of-hospital cardiac arrests. The AED delivered at least one defibrillation to each of 13 out of 16 people in ventricular defibrillation (81% sensitivity). The AED demonstrated a 100% specificity, not delivering any defibrillations to any of the 21 non-ventricular fibrillation rhythms (13 asystole, 8 other electrical rhythms); in two patients the rhythms could not be assessed.

Similar results were achieved by Weaver et al,¹² who studied the use of the AED by first-responding fire fighters on 260 victims of cardiac arrest. Of the 118 patients with ventricular fibrillation, 91 were given appropriate defibrillations (77% sensitivity). The AED also correctly identified all remaining non-ventricular fibrillation rhythms and did not deliver any inappropriate countershocks (100% specificity). Additionally, there were no accidental shocks reported to the rescuers themselves.

Although the specificity for measurable rhythms has been consistent at 100%, the sensitivity of delivered defibrillations has remained approximately 80%. However, most of these data were developed with first-generation AEDs. The single most common problem with these detection algorithms has been distinguishing asystole from fine ventricular fibrillation. Newer algorithms show promise to increase sensitivity for fine ventricular fibrillation without a loss in specificity.

Realistically, however, asystole always has a poor prognosis, in spite of all advanced cardiac life support measures. Therefore, the question of whether the AED was defibrillating fine ventricular fibrillation versus asystole is perhaps moot; the former rarely responds to electrical therapy,¹³ and the latter would not be adversely affected by defibrillation. In fact, a prospective study from UCLA found defibrillation of asystole more successful than standard drug therapy.¹⁴

Comments

Although early defibrillation by EMTs has been proven workable, and has been endorsed by several national organizations, it has yet to be implemented statewide and throughout the country. As public hearings of the state EMS task force continue, special emphasis should be given to the AED as a means of bringing an EMT-defibrillation program into reality.

The AEDs are less expensive than manual defibrillators. They eliminate the need for EMTs to be trained in interpretation of a dynamic rhythm strip for ventricular fibrillation before administering appropriate treatment; obviously, initial training and recertification at the EMT-defibrillation level would be simpler. Perhaps most important, there would be a more standardized level of care of the cardiac arrest victim throughout the state.

However, the idea of AEDs in an EMT-defibrillation program cannot come to fruition on its own merit. It will require the support of all emergency clinicians and academicians. It will require trained emergency physicians to provide medical control over basic EMTs, many of whom previously have operated without any medical supervision.

The AED offers a considerable potential for saving lives; let us not waste it. ■

Acknowledgment

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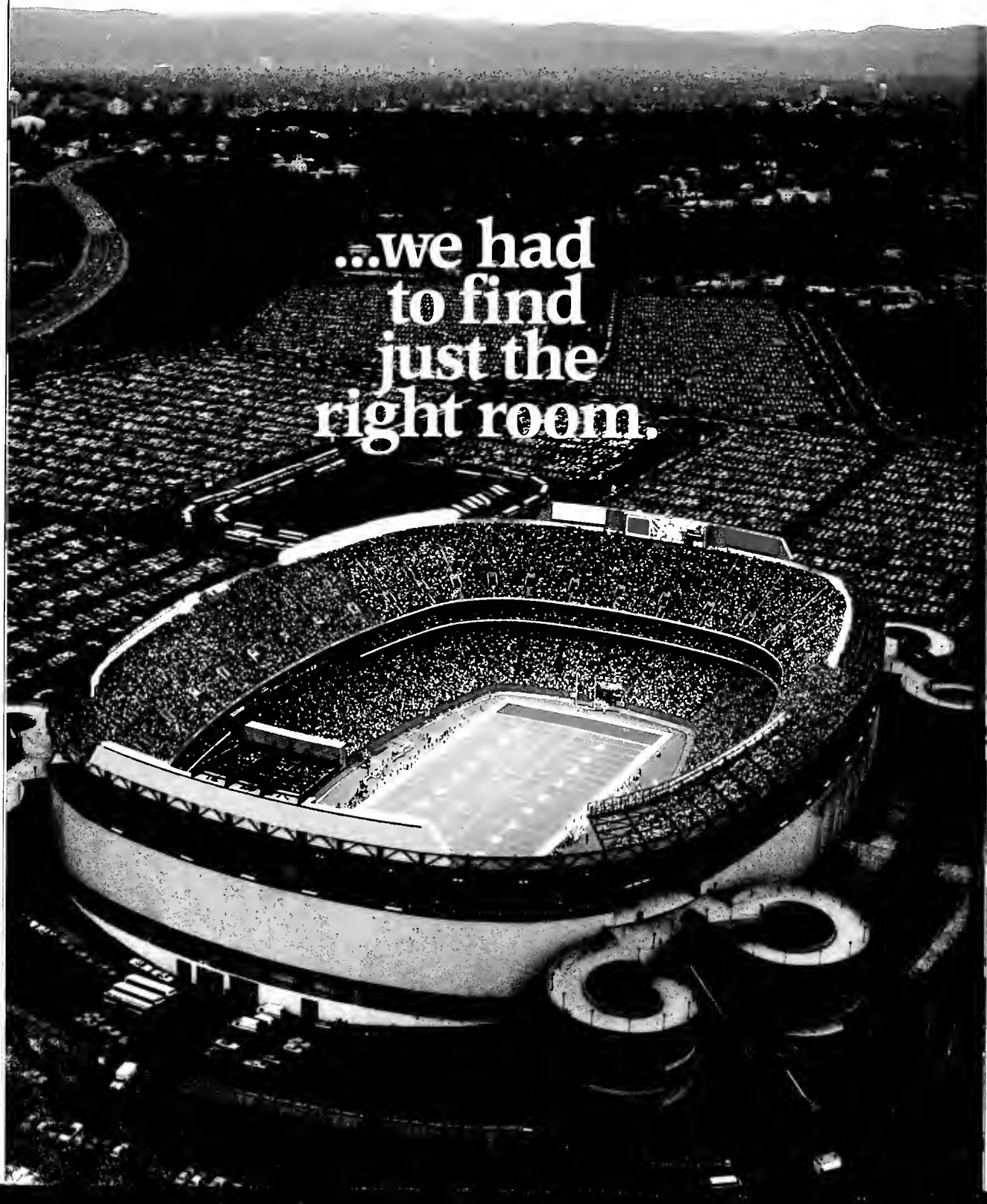
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Please see next page for brief summary of prescribing information

The one you know best keeps looking better

BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE CIRCULAR)

INDERAL® LA brand of propranolol hydrochloride (Long Acting Capsules)

DESCRIPTION. Inderal LA is formulated to provide a sustained release of propranolol hydrochloride. Inderal LA is available as 80 mg, 120 mg, and 160 mg capsules.

CLINICAL PHARMACOLOGY. Inderal is a nonselective beta-adrenergic receptor block agent possessing no other autonomic nervous system activity. It specifically competes with beta-adrenergic receptor stimulating agents for available receptor sites. When access to beta-receptor sites is blocked by Inderal, the chronotropic, inotropic, and vasodilator responses to beta-adrenergic stimulation are attenuated proportionately.

Inderal LA Capsules (80, 120, and 160 mg) release propranolol HCl at a controlled and predictable rate. Peak blood levels following dosing with Inderal LA occur at about 6 hours and the apparent plasma half-life is about 10 hours. When measured at steady state over a 24-hour period the areas under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of Inderal tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol resulting from the slower rate of absorption of propranolol. Over a twenty-four (24) hour period, blood levels are fairly constant for about twelve (12) hours then decline exponentially.

Inderal LA should not be considered a simple mg for mg substitute for conventional propranolol and the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to Inderal LA from conventional propranolol, a possible need for titration upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, Inderal LA has been therapeutically equivalent to the same mg dose of conventional Inderal, as assessed by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure and rate pressure product. Inderal LA can provide effective beta blockade for a 24-hour period.

The mechanism of the antihypertensive effect of Inderal has not been established. Among the factors that may be involved in the antihypertensive action are (1) decreased cardiac output, (2) inhibition of renin release by the kidneys, and (3) diminution of tonic sympathetic nerve outflow from vasomotor centers in the brain. Although total peripheral resistance may increase initially, it adjusts to or below the pretreatment level with chronic use. Effects on plasma volume appear to be minor and somewhat variable. Inderal has been shown to cause a small increase in serum potassium concentration when used in the treatment of hypertensive patients.

In angina pectoris, Inderal generally reduces the oxygen requirement of the heart at any given level of effort by blocking the catecholamine-induced increases in the heart rate, systolic blood pressure, and the velocity and extent of myocardial contraction. Propranolol may increase oxygen requirements by increasing left ventricular fiber length and diastolic pressure and systolic ejection period. The net physiologic effect of beta-adrenergic blockade is usually advantageous and is manifested during exercise by delayed onset of pain and increased work capacity.

In dosages greater than required for beta blockade, Inderal also exerts a quinidine-like or anesthetic-like membrane action which affects the cardiac action potential. The significance of the membrane action in the treatment of arrhythmias is uncertain.

The mechanism of the antiarrhythmic effect of propranolol has not been established. Beta-adrenergic receptors have been demonstrated in the pial vessels of the brain.

Beta receptor blockade can be useful in conditions in which, because of pathologic or functional changes, sympathetic activity is detrimental to the patient. But there are also situations in which sympathetic stimulation is vital. For example, in patients with severely damaged hearts, adequate ventricular function is maintained by virtue of sympathetic drive which should be preserved. In the presence of AV block, greater than first degree, beta blockade may prevent the necessary facilitating effect of sympathetic activity on conduction. Beta blockade results in bronchial constriction by interfering with adrenergic bronchodilator activity which should be preserved in patients subject to bronchospasm.

Propranolol is not significantly dialyzable.

INDICATIONS AND USAGE. Hypertension: Inderal LA is indicated in the management of hypertension, it may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. Inderal LA is not indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: Inderal LA is indicated for the long-term management of patients with angina pectoris.

Migraine: Inderal LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: Inderal LA is useful in the management of hypertrophic subaortic stenosis. Especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. Inderal LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. Inderal is contraindicated in 1) cardiogenic shock, 2) sinus bradycardia and greater than first degree block, 3) bronchial asthma, 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with Inderal.

WARNINGS. CARDIAC FAILURE. Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely or Inderal should be discontinued (gradually if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction following abrupt discontinuance of Inderal therapy. Therefore, when discontinuance of Inderal is planned the dosage should be gradually reduced over at least a few weeks, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If Inderal therapy is interrupted or an exacerbation of angina occurs, it is usually advisable to reinstitute Inderal therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema) — PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD NOT RECEIVE BETA BLOCKERS. Inderal should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY. The necessity or desirability of withdrawal of beta-blocking therapy prior

to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Inderal (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, e.g., dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOLYCEMIA. Beta-adrenergic blockade may prevent the appearance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more difficult to adjust the dosage of insulin.

HYPERHYDROSIS. Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid function tests.

PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME. Several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case, this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. General. Propranolol should be used with caution in patients with impaired hepatic or renal function. Inderal (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta-adrenergic blockade can cause reduction of intraocular pressure. Patients should be told that Inderal may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

Clinical Laboratory Tests. Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS. Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if Inderal is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncope, attacks or orthostatic hypotension.

Carcinogenesis, Mutagenesis, Impairment of Fertility. Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing dosages up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

Pregnancy. Pregnancy Category C. Inderal has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. Inderal should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. Inderal is excreted in human milk. Caution should be exercised when Inderal is administered to nursing women.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required withdrawal of therapy.

Cardiovascular: bradycardia, congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud type.

Central Nervous System: lightheadedness, mental depression manifested by insomnia, lassitude, weakness, fatigue, reversible mental depression progressing to cataplexy, visual disturbances, hallucinations, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometric tests.

Gastrointestinal: nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: bronchospasm.

Hematologic: agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: alopecia, LE-like reactions, psoriasisform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

DOSEAGE AND ADMINISTRATION. Inderal LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from Inderal tablets to Inderal LA capsules, care should be taken to assure that the desired therapeutic effect is maintained. Inderal LA should not be considered a simple mg for mg substitute for Inderal. Inderal LA has different kinetics and produces lower blood levels. Titration may be necessary especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION — Dosage must be individualized. The usual initial dosage is 80 mg Inderal LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood-pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily. In some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS — Dosage must be individualized. Starting with 80 mg Inderal LA once daily dosage should be gradually increased at three to seven day intervals until optimum response is obtained. Although individual patients may respond at any dosage level, the average optimum dosage appears to be 160 mg once daily in angina pectoris. The value and safety of dosage exceeding 320 mg per day have not been established.

If treatment is to be discontinued, reduce dosage gradually over a period of a few weeks (see WARNINGS).

MIGRAINE — Dosage must be individualized. The initial oral dose is 80 mg Inderal LA once daily. The usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimum migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximum dose, Inderal LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTROPIC SUBAORTIC STENOSIS — 80-160 mg Inderal LA once daily.

PEDIATRIC DOSAGE — At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

*The appearance of these capsules is a registered trademark of Ayerst Laboratories.

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Outpatient Microsurgical Management of Ruptured Lumbar Discs

Larry A. Rogers, M.D.

Computed tomography and microsurgical techniques enable safe outpatient treatment of some ruptured lumbar discs.

The reliability of computed tomography (CT)¹⁻⁴ and microsurgical techniques^{5,6} in managing patients with ruptured lumbar discs has been established. By combining these two methods it becomes possible to diagnose and treat these patients safely and effectively as outpatients. Potential savings in hospital costs are enormous.

This account of one surgeon's experience with 32 patients scheduled to have outpatient operations is illustrative. I shall also compare the results achieved in 68 patients undergoing microdiscectomy to those achieved in a similar group treated by laminectomy.

Clinical Material

Only patients suspected of having a virgin lumbar disc rupture not responding to conservative treatment are considered in this series. Patients with recurrent disc ruptures and patients in whom spondylosis appeared to be the offending lesion preoperatively are not included.

Between May, 1982 and December, 1985 all patients treated surgically for ruptured lumbar discs underwent microdiscectomy. For the last 21 months of this study microdiscectomy was performed on an outpatient basis in 32 of the 39 patients treated by the microsurgical method. During this period all patients with ruptured lumbar discs were treated with microsurgical operations, and no attempt was made to select patients for outpatient versus inpatient management. Of those treated as inpatients during this period, six were in the hospital at the time the decision to have

surgery was made: four had been admitted for myelography since outpatient CT scans were equivocal, and two were seen in consultation at the request of other physicians. An additional patient was hospitalized as an emergency during this period for control of severe pain. He had driven 80 miles for outpatient evaluation, and hospitalization was necessary to relieve his suffering while surgery was being scheduled.

Sixty-eight similar patients underwent "laminectomy" between December 1978 and May 1982. In each case an effort was made to remove the entire intervertebral disc through a generous laminotomy, followed by exposing the nerve root well laterally through a wide foramenotomy. Since May, 1981 microdiscectomy has been the surgical procedure of our preference for patients suspected of having a ruptured lumbar disc. An occasional laminectomy was performed between May 1981 and May 1982 primarily in obese patients and in those with less than compelling findings.

CT scans were performed in most cases with the GE 9800 high resolution scanner, and all were interpreted by an experienced neuroradiologist.

Laboratory tests, chest x-rays, and ECGs were obtained, when appropriate, on outpatients the day prior to surgery. All microsurgical operations were performed under general anesthesia in the neurosurgical operating theater, utilizing microsurgical techniques and the Zeiss OpMi-1 microscope equipped with a 300 mm lens and mounted on a Contraves stand. Exposures were achieved uniformly through 1-inch incisions, and only rarely was it necessary to remove any bone in order to visualize the affected nerve root and disc. Only the offending fragment was removed in the first 33 patients, while total discectomy was carried out during the last 35 microsurgical procedures.

From Charlotte Neurosurgical Associates, P.A., 1010 Edgehill Road North, Charlotte 28207.

Results

Table 1 compares patients undergoing microdiscectomy and laminectomy with respect to sex, age, mechanical and neurological findings, incidence of workmen's compensation and liability claims, radiographic means of diagnosis, and surgical pathology. Generally myelograms were performed on patients undergoing microdiscectomy only when the CT findings were equivocal. Myelography was the primary means of diagnosis among the laminectomy patients since lumbar spine CT scanning had not become a proven technique in our community at the time most of these patients were treated. Whether or not the fragment causing nerve root compression had escaped the confines of the outermost layer of the annulus fibrosis provides the distinction between rupture and extruded fragment, an extruded fragment being an entirely "free" fragment.

Microdiscectomy patients did not receive morphine or demerol or their equivalents in the postoperative period, and the majority took only aspirin or tylenol after the first two days. Codeine was the only controlled substance employed. Corticosteroids were not used, either topically in the operating room or in any form during the perioperative period.

Table 1

Clinical Characteristics of the Surgical Groups

	Microdiscectomy (68)	Laminectomy (68)
Average age	44.4 (27-78 yrs)	44.4 (25-78 yrs)
Sex:		
Men	38	37
Women	30	31
Straight leg sign present	56	65
Neurologic deficit:		
None	21	17
Sensory only	30	33
Motor only	2	4
Motor-sensory	8	9
Abnormal reflex only	7	5
Liability-Workman's Compensation	14	11
CT scan:		
# Studies done	51	4
Disc rupture	43 (84%)	3 (75%)
Equivocal	6 (12%)	1 (25%)
Spondylosis	2 (4%)	0
Myelogram:		
# Studies done	34	67
Disc rupture	32 (94%)	60 (90%)
Equivocal	2 (6%)	7 (10%)
Surgical Findings:		
Extruded fragment	27	24
Rupture	33	39
Bulging disc only	5	3
Spondylosis only	2	0
Negative	1	2

Table 2

Effect of Surgery on Leg Pain

	Week #3	Week #6
Microdiscectomy (68 patients)		
No pain	32 51	43 56
Occasional, slight	19	13
Slight pain	4	3
Less than preop	9	1
Same as preop	3	6
Worse	1	2
Laminectomy (68 patients)		
No pain	44 54	48 58
Occasional, slight	10	10
Slight pain	4	4
Less than preop	7	6
Same as preop	1	0
No data	2	0

Those patients treated as outpatients were generally ambulatory within three or four hours of surgery.

Of the 32 patients whose microdiscectomy was scheduled to be performed on an outpatient basis, only three required overnight hospitalization, and each of these was discharged the following morning. One experienced more back and leg pain than expected, another was kept at bedrest overnight because of a dural tear, and the third suffered severe nausea and vomiting following anesthesia.

Average hospital utilization was 1.09 days in the outpatient group, compared to 2.76 (range, 1-20) days of postoperative care in the microsurgical group overall. Laminectomy patients required an average of 7.19 (range, 3-15) days of postoperative care in the hospital.

Table 2 summarizes the efficiency of surgery in relieving lower extremity pain at three and six weeks. Neither operation appeared to be superior in this respect.

Patients were encouraged to return to work and full physical activities whenever they felt able. Table 3 indicates the number of patients working three, six, and ten weeks following surgery. Nearly one-third of the microsurgically treated patients had returned to full work responsibilities within three weeks, compared to only three of those treated by laminectomy. Even at six weeks the number of patients working in the microsurgical group was nearly twice that in the laminectomy group. Only after ten weeks did the number of patients working equalize between the two groups.

The primary difference in postoperative condition of patients in two groups was the amount of residual back discomfort and fear of back dysfunction. Significant back pain was unusual following microdiscectomy and decidedly rare

Table 3

Number of Patients Working Following Surgery

	Week #3	Week #6	Week #10
Microdiscectomy (68)	22	51	52
Laminectomy (68)	3	27	51

48 hours after surgery. Influenced by our experience in managing laminectomy patients for a number of years, we advised patients undergoing microdiscectomy early in the series to avoid such activities as jogging, tennis, and golf for three months. Recently, however, some patients have reported successful participation in such activities within six weeks of surgery without untoward effects.

Fourteen of 32 patients (44%) undergoing microdiscectomy as outpatients had returned to work within three weeks, compared to eight of 36 (22%) treated microsurgically as inpatients. Undoubtedly the strong sense of well-being engendered by the technique was a major factor in this phenomenon.

Of the 33 patients treated by removing only the ruptured fragment, seven (21%) developed a recurrence, six within a year. In the last 35 patients treated by the microsurgical method, in whom as much of the intervertebral disc as possible was removed, there have been no recurrences to date. There was only a single recurrence among the 68 patients undergoing standard surgical treatment and followed for a minimum of 42 months.

Four patients undergoing microdiscectomy experienced a complication. Two developed wound infections. One patient developed severe recurrent pain the day following surgery, and a CT scan subsequently demonstrated an epidural hematoma at the operative site which displaced the previously affected nerve root. Her pain resolved after two weeks of conservative treatment. Another developed a small pseudomeningocele several days following surgery which healed spontaneously after ten days of bedrest. Of the 68 patients undergoing standard laminectomy two wound infections were the only complications encountered.

Discussion

CT scanning methods and microsurgical techniques provide the potential for avoiding many of the problems long attendant to lumbar spine surgery for ruptured discs: back pain, prolonged hospitalization, and the complications of myelography. For the past several years we generally have relied upon computed tomography to confirm our clinical diagnosis of lumbar disc rupture, employing myelography only when scans were equivocal.

During this period of time, microdiscectomy has been performed almost exclusively once a diagnosis of primary disc rupture has been established, but only upon encountering a young woman three years ago with a ruptured disc and no hospitalization insurance did we consider attempting this operation on an outpatient basis. Since then we have treated 28 patients without overnight hospitalization, generally with good results, and with no notable untoward effects.

If computed tomography is to be employed as the primary means of radiographic diagnosis, the importance of top-quality studies cannot be over-emphasized. Examinations

from body scanners of limited resolution interpreted by radiologists not experienced in the nuances of spine diagnosis will result in unnecessary errors.

Reducing hospital utilization for postoperative care from an average of 7.19 days for patients treated by laminectomy to 1.09 days for microsurgically treated patients represents an enormous cost savings. When this savings in medical expense is coupled with the average patient's reduced period of absence from the work force, the true potential economic benefit of microdiscectomy is clear.

The technique of microdiscectomy will likely continue to evolve. Certainly whether a surgeon should remove the entire disc or only the offending fragment, as proposed by Williams,⁵ remains a controversial issue. Based on the high recurrence rate we experienced in our first 33 patients, in whom only the offending fragment was removed, we are convinced that the entire disc should be excised in every patient. Although additional follow-up will be necessary for confirmation, it seems reasonable to expect no greater recurrence rate among microsurgically treated patients than among those treated by more conventional techniques.

Conclusions

1. Microdiscectomy requires neither strong narcotics, corticosteroids, nor extensive bed rest during the postoperative period and is as effective as standard laminotomy, foramenotomy, and discectomy in relieving leg pain.
2. Patients undergoing microdiscectomy are more likely to return to work within three weeks of surgery than patients managed by laminectomy.
3. Microdiscectomy can be performed safely and effectively in an outpatient setting and is therefore a very cost-effective operation.
4. Removal of the entire disc appears to be preferable to the technique of removing only the ruptured fragment. ■

Acknowledgment

I would like to thank my colleagues, Drs. Jerry Petty, Bob Brawley, Jerry Greenhoot, Scott McLanahan and Craig Van Der Veer for their encouragement during this project, Mrs. Ruth Rankin for her technical assistance in the operating room, and Ms. Trudie Rodgers for her assistance in preparing the manuscript.

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MICROBIOLOGY The bactericidal activity of ceftriaxone results from inhibition of cell wall synthesis. Ceftriaxone has a high degree of stability in the presence of beta-lactamases, both penicillinases and cephalosporinases of gram-negative and gram-positive bacteria. Ceftriaxone is usually active against the following microorganisms *in vitro* and in clinical infections (see Indications and Usage):

GRAM-NEGATIVE AEROBES: *Enterobacter aerogenes*, *Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae* (including ampicillin-resistant strains), *H. parainfluenzae*, *Klebsiella species* (including *K. pneumoniae*), *Neisseria gonorrhoeae* (including penicillinase and nonpenicillinase-producing strains), *Neisseria meningitidis*, *Proteus mirabilis*, *Proteus vulgaris*, *Morganella morganii* and *Serratia marcescens*.

Note: Many strains of the above organisms that are multiply resistant to other antibiotics, e.g. penicillins, cephalosporins and aminoglycosides, are susceptible to ceftriaxone sodium. Ceftriaxone is also active against many strains of *Pseudomonas aeruginosa*.

GRAM-POSITIVE AEROBES: *Staphylococcus aureus* (including penicillinase-producing strains) and *Staphylococcus epidermidis* (Note: methicillin-resistant *Staphylococcus* are resistant to cephalosporins including ceftriaxone), *Streptococcus pyogenes* (Group A beta-hemolytic *Streptococcus*), *Streptococcus agalactiae* (Group B streptococci) and *Streptococcus pneumoniae* (Note: Most strains of enterococci, *Streptococcus faecalis* and Group D streptococci are resistant).

Ceftriaxone also demonstrates *in vitro* activity against the following microorganisms, although the clinical significance is unknown:

GRAM-NEGATIVE AEROBES: *Citrobacter freundii*, *Citrobacter diversus*, *Providencia species* (including *Providencia rettgeri*), *Salmonella species* (including *S. typhi*), *Shigella species* and *Acinetobacter calcoaceticus*.

ANAEROBES: *Bacteroides species*, *Clostridium species* (Note: most strains of *C. difficile* are resistant).

SUSCEPTIBILITY TESTING: Standard susceptibility disk method. Quantitative methods that require measurement of zone diameters give the most precise estimate of antibiotic susceptibility. One such procedure (Baier AW Kirby WMM Sherris JC Turck M: Antibiotic Susceptibility Testing by a Standardized Single Disk Method. *Am J Clin Pathol* 45:493-496, 1966; Standardized Disk Susceptibility Test. *Federal Register* 39:1982-19184, 1974; National Committee for Clinical Laboratory Standards, Approved Standard M7-A2M-2 Performance Standards for Antimicrobial Disk Susceptibility Tests, July 1975) has been recommended for use with disks to test susceptibility to ceftriaxone.

Laboratory results of the standardized single-disk susceptibility test using a 30 mcg ceftriaxone disk should be interpreted according to the following three criteria:

1. Susceptible organisms produce zones of 18 mm or greater, indicating that the tested organism is likely to respond to therapy.

2. Organisms that produce zones of 14 to 17 mm are expected to be susceptible if a high dosage (not to exceed 4 gm per day) is used or if the infection is confined to tissues and fluids (e.g., urine) in which high antibiotic levels are attained.

3. Resistant organisms produce zones of 13 mm or less, indicating that other therapy should be selected. Organisms should be tested with the ceftriaxone disk, since ceftriaxone has been shown by *in vitro* tests to be active against certain strains found resistant to cephalosporin class disks.

Organisms having zones of less than 18 mm around the cephalothin disk are not necessarily of intermediate susceptibility or resistant to ceftriaxone.

Standardized procedures require use of control organisms. The 30 mcg ceftriaxone disk should give zone diameters between 29 and 35 mm, 22 and 26 mm and 17 and 23 mm for the reference strains *E. coli* ATCC 25922, *S. aureus* ATCC 25923 and *P. aeruginosa* ATCC 27853, respectively.

DILUTION TECHNIQUES: Based on the pharmacokinetic profile of ceftriaxone, a bacterial isolate may be considered susceptible if the MIC value for ceftriaxone is not more than 16 mcg/ml. Organisms having an MIC value of less than 64 mcg/ml, but greater than 16 mcg/ml are expected to be susceptible if a high dosage (not to exceed 4 gm per day) is used or if the infection is confined to tissues and fluids (e.g., urine), in which high antibiotic levels are attained.

E. coli ATCC 25922, *S. aureus* ATCC 25923 and *P. aeruginosa* ATCC 27853 are also the recommended reference strains for controlling ceftriaxone dilution tests. Greater than 95% of MICs for the *E. coli* strain should fall within the range of 0.016 to 0.5 mcg/ml. The range for the *S. aureus* strain should be 1 to 2 mcg/ml, while for the *P. aeruginosa* strain the range should be 8 to 64 mcg/ml.

INDICATIONS AND USAGE: Rocephin is indicated for the treatment of the following infections when caused by susceptible organisms:

LOWER RESPIRATORY TRACT INFECTIONS: caused by *Strep. pneumoniae*, *Streptococcus species* (excluding enterococci), *Staph. aureus*, *H. influenzae*, *H. parainfluenzae*, *Klebsiella species* (including *K. pneumoniae*), *E. coli*, *E. aerogenes*, *Proteus mirabilis* and *Serratia marcescens*.

SKIN AND SKIN STRUCTURE INFECTIONS: caused by *Staph. aureus*, *Staph. epidermidis*, *Streptococcus species* (including enterococci), *E. cloacae*, *Klebsiella species* (including *K. pneumoniae*), *Proteus mirabilis* and *Pseudomonas aeruginosa*.

URINARY TRACT INFECTIONS (complicated and uncomplicated): caused by *E. coli*, *Proteus mirabilis*, *Proteus vulgaris*, *M. morganii* and *Klebsiella species* (including *K. pneumoniae*).

UNCOMPLICATED GONORRHEA (cervical, urethral and rectal): caused by *Neisseria gonorrhoeae*, including both penicillinase and nonpenicillinase-producing strains.

PELVIC INFLAMMATORY DISEASE: caused by *N. gonorrhoeae*.

BACTERIAL SEPTICEMIA: caused by *Staph. aureus*, *Strep. pneumoniae*, *E. coli*, *H. influenzae* and *K. pneumoniae*.

BONE AND JOINT INFECTIONS: caused by *Staph. aureus*, *Strep. pneumoniae*, *Streptococcus species* (excluding enterococci), *E. coli*, *P. mirabilis*, *K. pneumoniae* and *Enterobacter species*.

INTRA-ABDOMINAL INFECTIONS: caused by *E. coli* and *K. pneumoniae*.

MENINGITIS: caused by *H. influenzae*, *N. meningitidis* and *Strep. pneumoniae*. Ceftriaxone has also been used successfully in a limited number of cases of meningitis and shunt infections caused by *Staph. epidermidis* and *E. coli*.

PROPHYLAXIS: The administration of a single dose of ceftriaxone prophylactically may reduce the incidence of postoperative infections in patients undergoing coronary artery bypass surgery.

Although ceftriaxone has been shown to have been as effective as cefazolin in the prevention of infection following coronary artery bypass surgery, no placebo-controlled trials have been conducted to evaluate any cephalosporin antibiotic in the prevention of infection following coronary artery bypass surgery.

SUSCEPTIBILITY TESTING: Before instituting treatment with Rocephin, appropriate specimens should be obtained for isolation of the causative organism and for determination of its susceptibility to the drug.

Therapy may be instituted prior to obtaining results of susceptibility testing.

CONTRAINDICATIONS: Rocephin is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.

WARNINGS: Before therapy with ROCEPHIN IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS, PENICILLINS OR OTHER DRUGS. THIS PRODUCT SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. ANTIBIOTICS SHOULD BE ADMINISTERED WITH CAUTION TO ANY PATIENT WHO HAS DEMONSTRATED SOME FORM OF ALLERGY PARTICULARLY TO DRUGS. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE THE USE OF SUBCUTANEOUS EPINEPHRINE AND OTHER EMERGENCY MEASURES.

Pseudomembranous colitis has been reported with the use of cephalosporins (and other broad spec. from antibiotics); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use.

ROCEPHIN® (ceftriaxone sodium/Roche)

Treatment with broad spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis. Cholestyramine and colestipol resins have been shown to bind to the toxin *in vitro*. Mild cases of colitis respond to drug discontinuance alone. Moderate to severe cases should be managed with fluid, electrolyte and protein supplementation as indicated.

When the colitis is not relieved by drug discontinuance or when it is severe, oral vancomycin is the treatment of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should also be considered.

PRECAUTIONS: **GENERAL:** Although transient elevations of BUN and serum creatinine have been observed at the recommended dosages, the nephrotoxic potential of Rocephin is similar to that of other cephalosporins.

Ceftriaxone is excreted via both biliary and renal excretion (see Clinical Pharmacology). Therefore patients with renal failure normally require no adjustment in dosage when usual doses of Rocephin are administered, but concentrations of drug in the serum should be monitored periodically. If evidence of accumulation exists, dosage should be decreased accordingly.

Dosage adjustments should not be necessary in patients with hepatic dysfunction; however, in patients with both hepatic dysfunction and significant renal disease, Rocephin dosage should not exceed 2 gm daily without close monitoring of serum concentrations.

Alterations in prothrombin times have occurred rarely in patients treated with Rocephin. Patients with impaired vitamin K synthesis or low vitamin K stores (e.g., chronic hepatic disease and malnutrition) may require monitoring of prothrombin time during Rocephin treatment. Vitamin K administration (10 mg weekly) may be necessary if the prothrombin time is prolonged before or during therapy.

Prolonged use of Rocephin may result in overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken. Rocephin should be prescribed with caution in individuals with a history of gastrointestinal disease, especially colitis.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Carcinogenesis: Considering the maximum duration of treatment and the class of the compound, carcinogenicity studies with ceftriaxone in animals have not been performed. The maximum duration of animal toxicity studies was six months. Mutagenesis: Genetic toxicology tests included the Ames test, a micronucleus test and a test for chromosomal aberrations in human lymphocytes cultured *in vitro* with ceftriaxone. Ceftriaxone showed no potential for mutagenic activity in these studies.

Impairment of Fertility: Ceftriaxone produced no impairment of fertility when given intravenously to rats at doses up to 586 mg/kg/day, approximately 20 times the recommended clinical dose of 2 gm/day. **PREGNANCY:** Teratogenic Effects: Pregnancy Category B. Reproductive studies have been performed in mice and rats at doses up to 20 times the usual human dose and have no evidence of embryofetotoxicity or teratogenicity. In primates, no embryofetotoxicity or teratogenicity was demonstrated at a dose approximately three times the human dose.

There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response this drug should be used during pregnancy only if clearly needed.

Nonteratogenic Effects: In rats, in the Segment I (fertility and general reproduction) and Segment II (perinatal and postnatal) studies with intravenously administered ceftriaxone, no adverse effects were noted on various reproductive parameters during gestation and lactation, including postnatal growth, functional behavior and reproductive ability of the offspring at doses of 586 mg/kg/day, less.

NURSING MOTHERS: Low concentrations of ceftriaxone are excreted in human milk. Caution should be exercised when Rocephin is administered to a nursing woman.

PEDIATRIC USE: Safety and effectiveness of Rocephin in neonates, infants and children have been established for the dosages described in the Dosage and Administration section.

ADVERSE REACTIONS: Rocephin is generally well tolerated. In clinical trials, the following adverse reactions, which were considered to be related to Rocephin therapy or of uncertain etiology, were observed:

LOCAL REACTIONS:—pain, induration or tenderness at the site of injection (1%). Less frequently reported (less than 1%) was phlebitis after IV administration.

HYPERSENSITIVITY:—rash (1.7%). Less frequently reported (less than 1%) were pruritus, fever or chills. **HEMATOLOGIC:**—eosinophilia (6%), thrombocytosis (5%) and leukopenia (2.1%). Less frequently reported (less than 1%) were anemia, neutropenia, lymphopenia, thrombocytopenia and prolongation of the prothrombin time.

GASTROINTESTINAL:—diarrhea (2.7%). Less frequently reported (less than 1%) were nausea or vomiting and dysgeusia.

HEPATIC:—elevations of SGOT (3.1%) or SGPT (3.3%). Less frequently reported (less than 1%) were elevations of alkaline phosphatase and bilirubin.

RENAL:—elevations of the BUN (1.2%). Less frequently reported (less than 1%) were elevations of creatinine and the presence of casts in the urine.

CENTRAL NERVOUS SYSTEM:—headache or dizziness were reported occasionally (less than 1%).

GENITOURINARY:—moniliasis or vaginitis were reported occasionally (less than 1%).

MISCELLANEOUS:—diaphoresis and flushing were reported occasionally (less than 1%).

Other rarely observed adverse reactions (less than 0.1%) include leukocytosis, lymphocytosis, monocytosis, basophilia, a decrease in the prothrombin time, jaundice, glycosuria, hematuria, bronchospasm, serum sickness, abdominal pain, colitis, fulminant dyspepsia, palpitations and epistaxis.

DOSE AND ADMINISTRATION: Rocephin may be administered intravenously or intramuscularly. The usual adult daily dose is 1 to 2 gm given once a day (or in equally divided doses twice a day) depending on the type and severity of the infection. The initial daily dose should not exceed 4 grams.

For the treatment of serious miscellaneous infections in children, other than meningitis, the recommended total daily dose is 50 to 75 mg/kg (not to exceed 2 grams) given in divided doses every 12 hours.

Generally Rocephin therapy should be continued for at least two days after the signs and symptoms of infection have disappeared. The usual duration is 4 to 14 days, in complicated infections longer therapy may be required.

In the treatment of meningitis, a daily dose of 100 mg/kg (not to exceed 4 grams), given in divided doses every 12 hours, should be administered with or without a loading dose of 75 mg/kg.

For the treatment of uncomplicated gonococcal infections, a single intramuscular dose of 250 mg is recommended.

For preoperative use (surgical prophylaxis), a single dose of 1 gm administered ½ to 2 hours before surgery is recommended.

When treating infections caused by *Streptococcus pyogenes*, therapy should be continued for at least ten days.

No dosage adjustment is necessary for patients with impairment of renal or hepatic function; however, blood levels should be monitored in patients with severe renal impairment (e.g., dialysis patients) and in patients with both renal and hepatic dysfunction.

HOW SUPPLIED: Rocephin (ceftriaxone sodium/Roche) is supplied as a sterile crystalline powder in glass vials and piggyback bottles. The following packages are available:

Vials containing 250 mg equivalent of ceftriaxone: Boxes of 10 (NDC 0004 1962 01).

Vials containing 500 mg equivalent of ceftriaxone: Boxes of 10 (NDC 0004 1963 01).

Vials containing 1 gm equivalent of ceftriaxone: Boxes of 10 (NDC 0004 1964 01).

Piggyback bottles containing 1 gm equivalent of ceftriaxone: Boxes of 10 (NDC 0004 1964 03).

Vials containing 2 gm equivalent of ceftriaxone: Boxes of 10 (NDC 0004 1965 01).

Piggyback bottles containing 2 gm equivalent of ceftriaxone: Boxes of 10 (NDC 0004 1965 03).

Bulk pharmacy containers, containing 10 gm equivalent of ceftriaxone: Boxes of 10 (NDC 0004 1971 01).

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Roche Laboratories

Division of Hoffmann-La Roche Inc.

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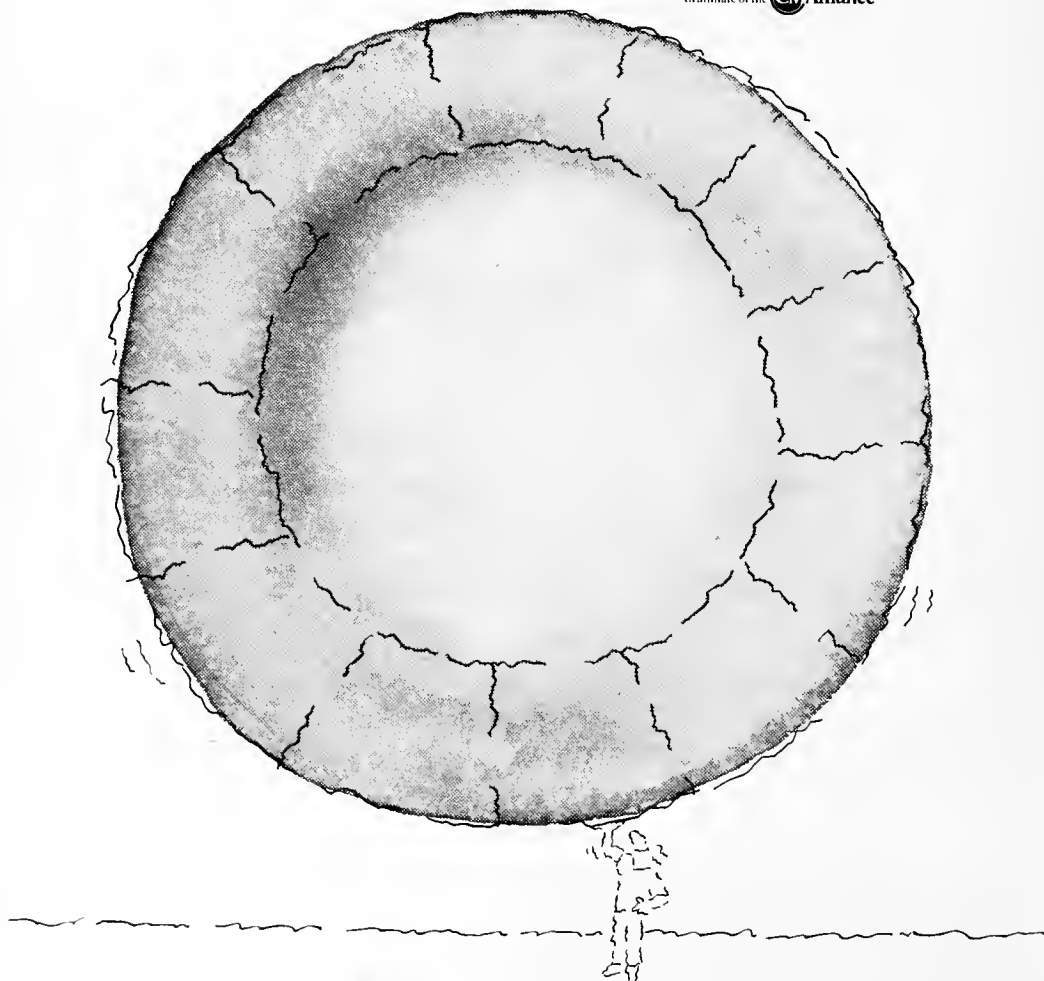
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CONTRAINDICATIONS: 1) Severe left ventricular dysfunction (see WARNINGS), 2) Hypotension (less than 90 mmHg systolic pressure) or cardiogenic shock, 3) Sick sinus syndrome or 2nd or 3rd degree AV block (except in patients with a functioning artificial ventricular pacemaker).

WARNINGS: **Heart Failure:** ISOPTIN should be avoided in patients with severe left ventricular dysfunction (see DRUG INTERACTIONS). Patients with milder ventricular dysfunction should, if possible, be controlled before verapamil treatment. **Hypotension:** ISOPTIN (verapamil HCl) may produce occasional symptomatic hypotension. **Elevated Liver Enzymes:** Elevations of transaminases with and without concomitant elevations in alkaline phosphatase and bilirubin have been reported. Periodic monitoring of liver function in patients receiving verapamil is therefore prudent. **Accessory Bypass Tract (Wolff-Parkinson-White):** Patients with paroxysmal and/or chronic atrial flutter or atrial fibrillation and a coexisting accessory AV pathway have developed increased antegrade conduction across the accessory pathway producing a very rapid ventricular response or ventricular fibrillation after receiving intravenous verapamil. While this has not been reported with oral verapamil, it should be considered a potential risk. Treatment is usually 0 C-c cardioversion. **Atrioventricular Block:** The effect of verapamil on AV conduction and the SA node may cause asymptomatic 1st degree AV block and transient bradycardia. Higher degrees of AV block, while infrequent (0.6%), may require a reduction in dosage or, in rare instances, discontinuation of verapamil HCl. Patients with Hypertrophic Cardiomyopathy (HHS): Although verapamil has been used in the therapy of patients with HHS, severe cardiovascular decompensation and death have been noted in this patient population.

PRECAUTIONS: **Impaired Hepatic or Renal Function:** Verapamil is highly metabolized by the liver with about 70% of an administered dose excreted in the urine. In patients with impaired hepatic or renal function verapamil should be administered cautiously and the patients monitored for abnormal prolongation of the PR interval or other signs of excessive pharmacological effects (see OVERDOSAGE).

Drug Interactions: **Beta Blockers:** Concomitant use of ISOPTIN and oral beta-adrenergic blocking agents may be beneficial in certain patients with chronic stable angina or hypertension, but available information is not sufficient to predict with confidence the effects of concurrent treatment in patients with left ventricular dysfunction or cardiac conduction abnormalities. **Digitalis:** Clinical use of verapamil in digitalized patients has shown the combination to be well tolerated if digoxin doses are properly adjusted. However, chronic verapamil treatment increases serum digoxin levels by 50 to 75% during the first week of therapy and this can result in digitalis toxicity. Upon discontinuation of ISOPTIN (verapamil HCl), the patient should be reassessed to avoid underdigitalization. **Antihypertensive Agents:** Verapamil administered concomitantly with oral antihypertensive agents (e.g., vasodilators, angiotensin-converting enzyme inhibitors, diuretics, beta blockers, prazosin) will usually have an additive effect on lowering blood pressure. Patients receiving these combinations should be appropriately monitored. **Disopyramide:** Disopyramide should not be administered within 48 hours before or 24 hours after verapamil administration. **Quinidine:** In patients with hypertrophic cardiomyopathy (HHS), concomitant use of verapamil and quinidine resulted in significant hypotension. There has been a report of increased quinidine levels during verapamil therapy. **Nitrates:** The pharmacologic profile of verapamil and nitrates as well as clinical experience suggest beneficial interactions. **Cimetidine:** Two clinical trials have shown a lack of significant verapamil interaction with cimetidine. A third study showed cimetidine reduced verapamil clearance and increased elimination to 1/2. **Anesthetic Agents:** Verapamil may potentiate the activity of neuromuscular blocking agents and inhalation anesthetics. **Carbamazepine:** Verapamil may increase carbamazepine concentrations during combined therapy. **Rifampin:** Therapy with rifampin may markedly reduce oral verapamil bioavailability. **Lithium:** Verapamil may lower lithium levels in patient on chronic oral lithium therapy. **Carcinogenesis:** Mutagenesis, impairment of fertility. There was no evidence of a carcinogenic potential of verapamil administered to rats for two years. Verapamil was not mutagenic in the Ames test. Studies in female rats did not show impaired fertility. Effects on male fertility have not been determined. **Pregnancy (Category C):** There are no adequate and well-controlled studies in pregnant women. ISOPTIN crosses the placental barrier and can be detected in umbilical vein blood at delivery. This drug should be used during pregnancy, labor, and delivery, only if clearly needed. **Nursing Mothers:** ISOPTIN is excreted in human milk, therefore, nursing should be discontinued while verapamil is administered. **Pediatric Use:** Safety and efficacy of ISOPTIN in children below the age of 18 years have not been established.

ADVERSE REACTIONS: Constipation 8.4%, dizziness 3.5%, nausea 2.7%, hypotension 2.5%, edema 2.1%, headache 1.9%, CHF/pulmonary edema 1.8%, fatigue 1.7%, bradycardia 1.4%, 3° AV block 0.8%, flushing 0.1%, elevated liver enzymes (see WARNINGS). The following reactions, reported in less than 1.0% of patients, occurred under conditions (open trials, marketing experience) where a causal relationship is uncertain; they are mentioned to alert the physician to a possible relationship: angina pectoris, arthralgia and rash, AV block, blurred vision, cerebrovascular accident, chest pain, claudication, confusion, diarrhea, dry mouth, dyspnea, ecchymosis or bruising, equilibrium disorders, exanthema, gastrointestinal distress, gingival hyperplasia, gynecomastia, hair loss, hyperkeratosis, impotence, increased urination, insomnia, macules, muscle cramps, myocardial infarction, palpitations, paresthesia, psychotic symptoms, purpura (vasculitis), shakiness, somnolence, spotty menstruation, sweating, syncope, urticaria. **Treatment of Acute Cardiovascular Adverse Reactions:** Whenever severe hypotension or complete AV block occur following oral administration of verapamil, the appropriate emergency measures should be applied immediately, e.g., intravenously administered isoproterenol HCl, levalterenol bitartrate, atropine (all in the usual doses), or calcium gluconate (10% solution). If further support is necessary, inotropic agents (dopamine or dobutamine) may be administered. Actual treatment and dosage should depend on the severity and the clinical situation and the judgment and experience of the treating physician.

OVERDOSAGE: Treatment of overdosage should be supportive. Beta-adrenergic stimulation or parenteral administration of calcium solutions may increase calcium ion flux across the slow channel, and have been used effectively in treatment of deliberate overdosage with verapamil. Clinically significant hypotensive reactions or fixed high degree AV block should be treated with vasopressor agents or cardiac pacing, respectively. Asystole should be handled by the usual measures including cardiopulmonary resuscitation.

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A Review of the Basics of Closed Thoracic Drainage

J. Steve Julian, M.D., and Timothy C. Pennell, M.D.

Over the last 20 years the treatment of critically ill patients has become tremendously sophisticated, and it is now routine to "plug" the intensive care unit patient to a ventilator, a Swan-Ganz catheter, computerized monitors, and calibrated infusion pumps. Not infrequently, the patient will also need to have closed thoracic drainage as a result of trauma, infection, surgery, or barotrauma. The closed pleural drainage system is simple, yet seldom understood. Our purpose here is to review briefly the basic principles and practical aspects of closed thoracic drainage with applied negative suction.

The concept of closed pleural drainage originated in England in the 1870s. Among the earliest descriptions of closed continuous irrigation and aspiration of the pleural space is that of Hewett in 1876.¹ In the early 1900s, Kenyon² reported using a closed drainage system for the treatment of empyema in children. In 1922 Lilienthal³ described the use of closed suction drainage following the surgical treatment of bronchiectasis.

The purpose of a closed thoracic drainage system is to generate a negative pressure within the pleural space to promote fluid evacuation and lung expansion. If there has been no disruption of the visceral pleura or lung parenchyma, there is no absolute requirement for the application of suction in closed thoracic drainage. A simple water seal (figure 1) will serve as a one-way valve, permitting egress of pleural fluid or air while preventing reentry of air into the pleural space. The expanding intact lung and any negative pressure generated by fluid contained within nondependent tubing (length B in figure 1) combine to promote obliteration of the pleural space.

It must be recognized, however, that the force favoring

lung expansion will be opposed by an opposite force. This force will be equal in centimeters of water to the pressure created by the column of water in the long tubing beneath the fluid level in the collection bottle (length A in figure 1), and, as drainage accumulates, the force necessary to expel the pleural fluid or air will increase as the length of long tubing becomes further submersed. Because of this factor, we routinely use a three-bottle vacuum suction device for all cases of thoracic drainage.

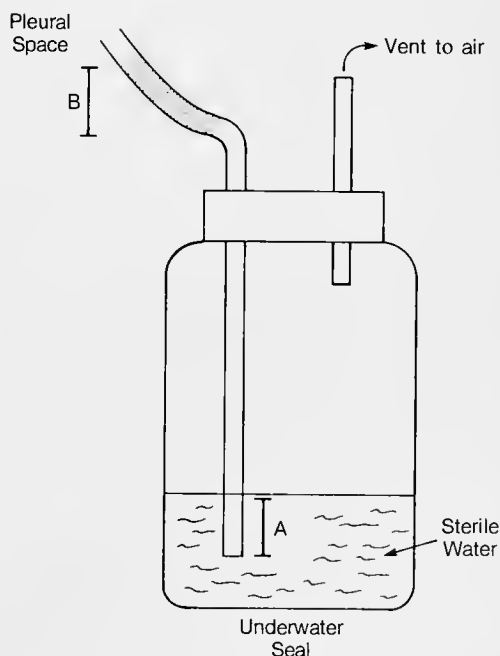


Figure 1. Simple underwater seal apparatus.

Standard Three Bottle Suction Total Applied Suction = B - A

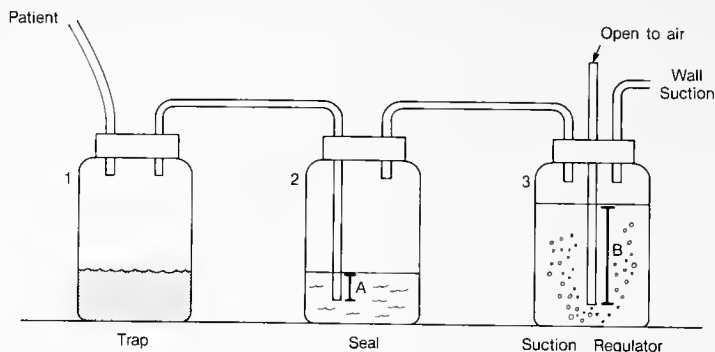


Figure 2. Standard three-bottle suction.

Basic Components

The closed thoracic suction drainage system has three basic components (figure 2): the trap, the water seal, and the suction regulator or water manometer.⁴ These provide for closed vacuum aspiration of the pleural space and a flow capacity in excess of any pulmonary air leak.⁵ The readily available wall vacuum is used as a negative pressure source with an interposed flow regulator valve (figure 3).

The first bottle in the system is the trap. The trap collects drainage from the pleural space, permitting ease of inspection, quantitation, and sampling in a sterile manner. The trap somewhat simplifies the physics of the system, in that there is no accumulation of fluid in the water seal, and thereby no progressive reduction in the applied intrathoracic pressure. This fact will become more apparent when we view the system as a whole.

The second bottle is the water seal. The seal is necessary to partition the intrathoracic space from the environment and to prevent uncontrolled to-and-fro movement of air with respiration. As long as the tip of the long tubing is beneath the water level (usually for a length of 1.5 to 3 cm; length A in figure 2), a seal exists exclusive of leakage around the bottle stoppers, tubing connectors, or chest tube insertion site. As implied earlier, it is important to realize the significance of the length of tubing beneath the water level. The negative pressure applied to the intrathoracic space by this system will be diminished (in cm H₂O) by the length of tubing (length A) beneath the fluid level. It is also important to note that this bottle is useful in any assessment of continued air leak and of proper tube positioning as described below.

The third bottle in the system is the suction regulator, or water manometer (figure 2). This bottle is almost completely



Figure 3. Standard three-bottle suction apparatus with suction regulator valve.

Four Bottle Method to Increase Applied Suction

Total Applied Suction = $B + B' - A$

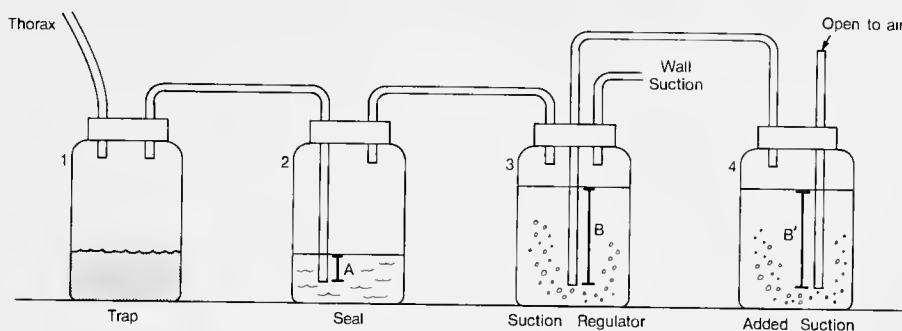


Figure 4. Four-bottle suction system.

filled with sterile water. The two short tubes above the water level conduct the vacuum, but the long tube is the true vacuum regulator or manometer. The long tube is open to the atmosphere. The negative pressure generated by the system and applied to the pleural space is determined by the extent of long tube beneath the air-water interface (distance B in figure 2). More, or less, suction is generated by lowering, or raising, this tube. The total amount of negative pressure applied by the system, then, is B (bottle 3) minus A (bottle 2).

Putting the three bottles in series with a properly placed chest tube and connecting them, as illustrated, to a high vacuum source via a flow regulator valve (figure 3) constitutes a closed pleural suction apparatus. With vacuum applied, bubbling occurs in the third bottle. The vigorosity of the bubbling is controlled by the flow regulator valve, which thus governs the rate of gas flow in the system. The importance and implications of high flow in such a system have been well documented.⁶ Basically, flow must be sufficient to cause no impedance to the movement of gas or liquid from the pleural space.

In inspecting the system it is again necessary to appreciate that the amount of negative pressure generated intrathoracically is determined by the level of the water manometer (length B in figure 2). Any attempt to increase the negative pressure generated by the system requires lengthening the manometer as described by Roe⁵ or adding a bottle or bottles connected into the system as depicted in figure 4. With a fourth bottle added, the total negative pressure applied to the thorax equals $B + B' - A$. The most common error made by the infrequent users of closed thoracic drainage is the incorrect placement of additional bottles for increasing this intrapleural negative pressure. Therefore, figure 4 should be studied carefully. If a Pleur-evac[®] or similar manufactured system is being used, increased negative pressure above that obtainable with water alone can be generated by the addition of 1 to 2 cm of liquid mercury to the bubble chamber (figure 5, next page). The effect will be to increase the

suction generated, and the amount may be estimated by taking into account the fact that 1 cm of mercury is equivalent to 13.6 cm of water.

Applications

An understanding of the closed thoracic drainage system and of the factors that diminish its effectiveness will improve its application in clinical practice.

First, it must be recognized that any dependent fluid-filled loops of tubing oppose the suction created by the regulator.⁷ Thus, the tubing should not hang haphazardly from the bedside, but should be positioned alongside the bed in a horizontal plane leading to the drainage collector.

Second, as would be expected, any air leak diminishes the negative force applied. All stoppers and tubing connectors must be sealed, and the site of exit of the tube from the patient's chest wall must be made air-tight through the use of occlusive dressings, purse string sutures, or both. If the system itself is leak-free, any continued pleural air leak can be assessed by examining the water seal bottle with the suction disconnected: any bubbling in the second bottle (the water seal in figure 2) with respiration is a positive sign of continued pulmonary air leak.

Third, the level of fluid in the water seal tube (as well as any slugs of fluid in the tubing) should gently rise and fall with respiration. Absence of such "tidal flow" suggests malpositioning of the tube outside the pleural cavity or occlusion of the tube with a fibrin clot.

Fourth, the manufactured systems (e.g., Pleur-evac[®]), although altered in form, work on the same principle and function in the same way. Choosing which system to use is a matter of personal preference and price. In our hospital the three-bottle system costs \$34 less than any of the manufactured systems.

Finally, an air leak, with or without pneumothorax, may continue despite all efforts to correct it. In this instance, a

Manufactured Suction Apparatus

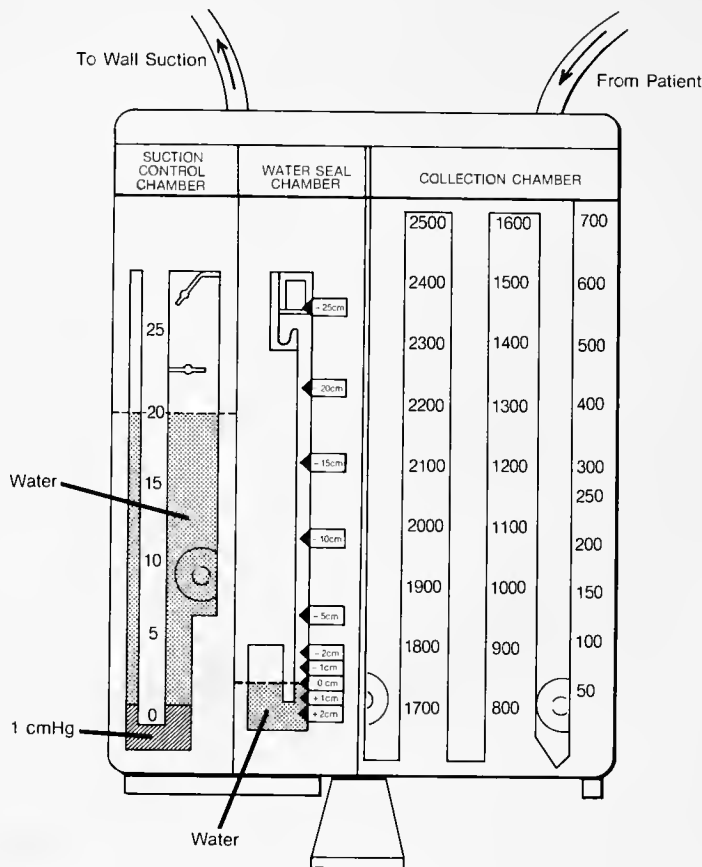


Figure 5. Disposable system containing 1 cm of liquid mercury (Hg) in suction control chamber to increase intrapleural suction.

bronchopleural fistula is often the problem. A fistula located in the peripheral airways can often be closed by placing a Heimlich valve (figure 6) on the chest tube in place of any suction apparatus. This one-way valve permits the egress of air or fluid while preventing pneumothorax. With this device in place, the patient is mobilized and, in fact, can be discharged with the chest tube/valve in place for follow-up as an outpatient. Before the tube is removed, it is appropriate to obtain a chest roentgenogram with the tube clamped, to rule out the development of pneumothorax.

Removal of the System

An important consideration in the management of thoracic drainage is when to remove the tube from the pleural space. When a tube placed for fluid or empyema drains less than

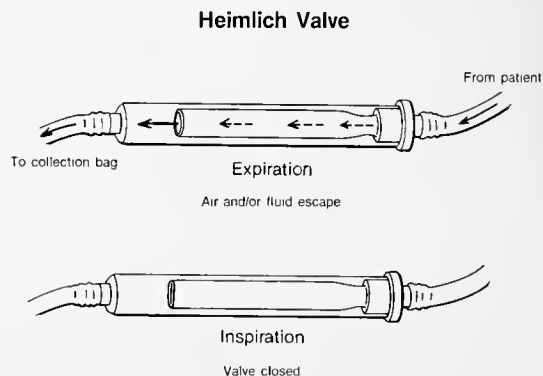


Figure 6. Standard Heimlich valve.

75 ml/24 hours and the chest roentgenogram shows no significant accumulation of fluid, the tube usually can be removed. When a tube is placed for pneumothorax alone, after an adequate period of applied suction (two to four days) it should be placed on water seal (i.e., the suction should be discontinued) for 24 hours. A chest roentgenogram showing no pneumothorax, combined with the absence of air bubbles in the water seal bottle when the patient is asked to cough deeply (indicating the absence of air leak at the bedside), is sufficient indication that the tube may be removed safely.

Some clinicians prefer to clamp the chest tube near the thorax and to obtain a chest roentgenogram to exclude the development of pneumothorax before removing the tube. We do not use this method except when using a chest tube with a Heimlich valve for chronic drainage. There is some danger of tension pneumothorax developing after clamping. We instruct our personnel never to clamp a chest tube, especially when a patient is being transported or moved about, since it is much safer for gas or fluid to be expelled freely from the chest through a water seal than to be trapped within the chest by a "clamped" chest tube.

In conclusion, caring for the critically ill patient requires an understanding of the information provided by complex monitoring devices and of advanced therapeutics. A less

complicated but frequently used device that all team members should be familiar with is closed thoracic drainage with applied suction. It was our goal in this article to describe the components of that system and emphasize some of the aspects of its clinical application. ■

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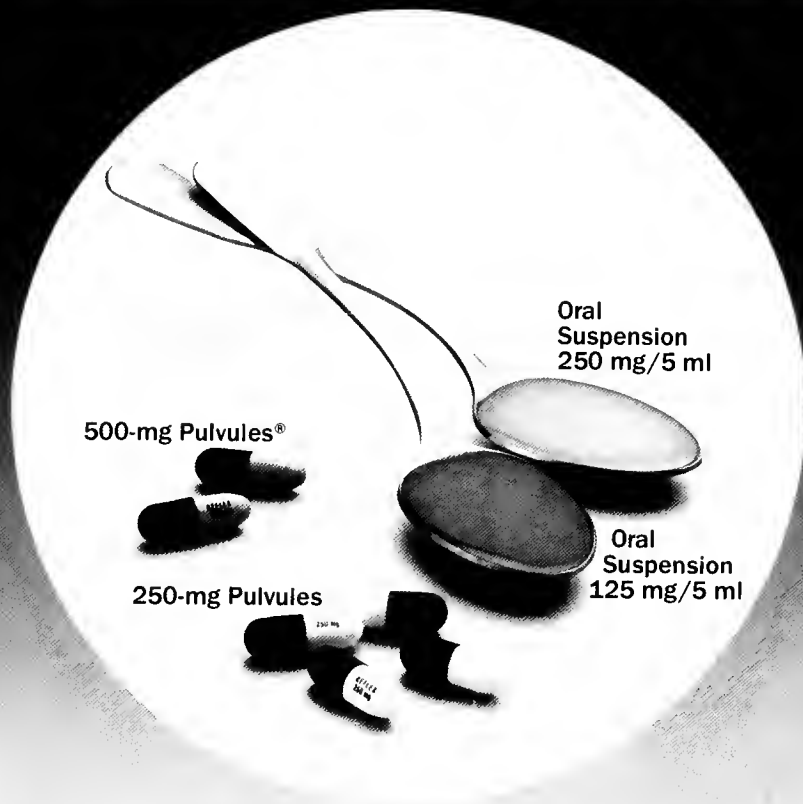
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Please see brief summary of Glucotrol® (glipizide) prescribing information on next page.

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Reference

1. Sachs R, Frank M, Fishman SA. Overview of clinical experience with glipizide. In *Glipizide: A Worldwide Review*. Princeton, NJ: Excerpta Medica; 1984. pp 163-172.

GLUCOTROL® (glipizide) Tablets

Brief Summary of Prescribing Information

INDICATIONS AND USAGE: GLUCOTROL is indicated as an adjunct to diet for the control of hyperglycemia in patients with non-insulin-dependent diabetes mellitus (NIDDM, type II) after an adequate trial of dietary therapy has proved unsatisfactory.

CONTRAINDICATIONS: GLUCOTROL is contraindicated in patients with known hypersensitivity to the drug or with diabetic ketoacidosis, with or without coma, which should be treated with insulin.

SPECIAL WARNING ON INCREASED RISK OF CARDIOVASCULAR MORTALITY: The administration of oral hypoglycemic drugs has been reported to be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin. This warning is based on the study conducted by the University Group Diabetes Program (UGDP), a long-term prospective clinical trial designed to evaluate the effectiveness of glucose-lowering drugs in preventing or delaying vascular complications in patients with non-insulin-dependent diabetes. The study involved 823 patients who were randomly assigned to one of four treatment groups (Diabetes, 19, supp. 2:747-830, 1970).

UGDP reported that patients treated for 5 to 8 years with diet plus a fixed dose of tolbutamide (1.5 grams per day) had a rate of cardiovascular mortality approximately 2 1/2 times that of patients treated with diet alone. A significant increase in total mortality was not observed, but the use of tolbutamide was discontinued based on the increase in cardiovascular mortality, thus limiting the opportunity for the study to show an increase in overall mortality. Despite controversy regarding the interpretation of these results, the findings of the UGDP study provide an adequate basis for this warning. The patient should be informed of the potential risks and advantages of GLUCOTROL, and of alternative modes of therapy.

Although only one drug in the sulfonylurea class (tolbutamide) was included in this study, it is prudent from a safety standpoint to consider that this warning may also apply to other oral hypoglycemic drugs in this class, in view of their close similarities in mode of action and chemical structure.

PRECAUTIONS: Renal and Hepatic Disease: The metabolism and excretion of GLUCOTROL may be slowed in patients with impaired renal and/or hepatic function. Hypoglycemia may be prolonged in such patients should it occur.

Hypoglycemia: All sulfonylureas are capable of producing severe hypoglycemia. Proper patient selection, dosage, and instructions are important to avoid hypoglycemia. Renal or hepatic insufficiency may increase the risk of hypoglycemic reactions. Elderly, debilitated or malnourished patients and those with adrenal or pituitary insufficiency are particularly susceptible to the hypoglycemic action of glucose-lowering drugs. Hypoglycemia may be difficult to recognize in the elderly or people taking beta-adrenergic blocking drugs. Hypoglycemia is more likely to occur when caloric intake is deficient, after severe or prolonged exercise, when alcohol is ingested, or when more than one glucose-lowering drug is used.

Loss of Control of Blood Glucose: A loss of control may occur in diabetic patients exposed to stress such as fever, trauma, infection or surgery. It may then be necessary to discontinue GLUCOTROL and administer insulin.

Laboratory Tests: Blood and urine glucose should be monitored periodically. Measurement of glycosylated hemoglobin may be useful.

Information for Patients: Patients should be informed of the potential risks and advantages of GLUCOTROL, of alternative modes of therapy, as well as the importance of adhering to dietary instructions, of a regular exercise program, and of regular testing of urine and/or blood glucose. The risks of hypoglycemia, its symptoms and treatment, and conditions that predispose to its development should be explained to patients and responsible family members. Primary and secondary failure should also be explained.

Drug Interactions: The hypoglycemic action of sulfonylureas may be potentiated by certain drugs including non-steroidal anti-inflammatory agents and other drugs that are highly protein bound, salicylates, sulfonamides, chloramphenicol, probenecid, coumarins, monoamine oxidase inhibitors, and beta-adrenergic blocking agents. In vitro studies indicate that GLUCOTROL binds differently than tolbutamide and does not interact with salicylate or dicumarol. However, caution must be exercised in extrapolating these findings to a clinical situation. Certain drugs tend to produce hyperglycemia and may lead to loss of control, including the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoprenaline. A potential interaction between oral miconazole and oral hypoglycemic agents leading to severe hypoglycemia has been reported. Whether this interaction also occurs with the intravenous, topical, or vaginal preparations of miconazole is not known.

Carcinogenesis, Mutagenesis, Impairment of Fertility: A 20-month study in rats and an 18-month study in mice at doses up to 75 times the maximum human dose revealed no evidence of drug-related carcinogenicity. Bacterial and in vivo mutagenicity tests were uniformly negative. Studies in rats of both sexes at doses up to 75 times the human dose showed no effects on fertility.

Pregnancy: Pregnancy Category C. GLUCOTROL (glipizide) was found to be mildly fetotoxic in rat reproductive studies at all dose levels (5-50 mg/kg). This fetotoxicity has been similarly noted with other sulfonylureas, such as tolbutamide and tolazamide. The effect is perinatal and believed to be directly related to the pharmacologic (hypoglycemic) action of GLUCOTROL. In studies in rats and rabbits no teratogenic effects were found. There are no adequate and well-controlled studies in pregnant women. GLUCOTROL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Because recent information suggests that abnormal blood glucose levels during pregnancy are associated with a higher incidence of congenital abnormalities, many experts recommend that insulin be used during pregnancy to maintain blood glucose levels at close to normal as possible.

Neonatal Effects: Prolonged severe hypoglycemia has been reported in neonates born to mothers who were receiving a sulfonylurea drug at the time of delivery. This has been reported more frequently with the use of agents with prolonged half-lives. GLUCOTROL should be discontinued at least one month before the expected delivery date.

Nursing Mothers: Since some sulfonylurea drugs are known to be excreted in human milk, insulin therapy should be considered if nursing is to be continued.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: In controlled studies, the frequency of serious adverse reactions reported was very low. Of 702 patients, 11.8% reported adverse reactions and in only 1.5% was GLUCOTROL discontinued.

Hypoglycemia: See PRECAUTIONS and OVERDOSEAGE sections.

Gastrointestinal: Gastrointestinal disturbances, the most common, were reported with the following approximate incidence: nausea and diarrhea, one in 70; constipation and gastralgia, one in 100. They appear to be dose-related and may disappear on division or reduction of dosage. Cholestatic jaundice may occur rarely with sulfonylureas. GLUCOTROL should be discontinued if this occurs.

Dermatologic: Allergic skin reactions including erythema, morbilliform or maculopapular eruptions, urticaria, pruritus, and eczema have been reported in about one in 70 patients. These may be transient and may disappear despite continued use of GLUCOTROL. If skin reactions persist, the drug should be discontinued. Porphyria cutanea tarda and photosensitivity reactions have been reported with sulfonylureas.

Hematologic: Leukopenia, agranulocytosis, thrombocytopenia, hemolytic anemia, aplastic anemia, and pancytopenia have been reported with sulfonylureas.

Metabolic: Hepatic porphyria and disulfiram-like alcohol reactions have been reported with sulfonylureas. Clinical experience to date has shown that GLUCOTROL has an extremely low incidence of disulfiram-like reactions.

Endocrine Reactions: Cases of hyponatremia and the syndrome of inappropriate antidiuretic hormone (SIADH) secretion have been reported with this and other sulfonylureas.

Miscellaneous: Dizziness, drowsiness, and headache have been reported in about one in fifty patients treated with GLUCOTROL. They are usually transient and seldom require discontinuance of therapy.

OVERDOSEAGE: Overdosage of sulfonylureas including GLUCOTROL can produce hypoglycemia. If hypoglycemic coma is diagnosed or suspected, the patient should be given a rapid intravenous injection of concentrated (50%) glucose solution. This should be followed by a continuous infusion of a more dilute (10%) glucose solution at a rate that will maintain the blood glucose at a level above 100 mg/dL. Patients should be closely monitored for a minimum of 24 to 48 hours since hypoglycemia may recur after apparent clinical recovery. Clearance of GLUCOTROL from plasma would be prolonged in persons with liver disease. Because of the extensive protein binding of GLUCOTROL (glipizide), dialysis is unlikely to be of benefit.

DOSEAGE AND ADMINISTRATION: There is no fixed dosage regimen for the management of diabetes mellitus with GLUCOTROL; in general, it should be given approximately 30 minutes before a meal to achieve the greatest reduction in postprandial hyperglycemia.

Initial Dose: The recommended starting dose is 5 mg before breakfast. Geriatric patients or those with liver disease may be started on 2.5 mg. Dosage adjustments should ordinarily be in increments of 2.5-5 mg, as determined by blood glucose response. At least several days should elapse between titration steps.

Maximum Dose: The maximum recommended total daily dose is 40 mg.

Maintenance: Some patients may be effectively controlled on a once-a-day regimen, while others show better response with divided dosing. Total daily doses above 15 mg should ordinarily be divided.

HOW SUPPLIED: GLUCOTROL is available as white, dye-free, scored diamond-shaped tablets imprinted as follows: 5 mg tablet—Pizer 411 (NDC 5 mg 0049-4110-66) Bottles of 100, 10 mg tablet—Pizer 412 (NDC 10 mg 0049-4120-65) Bottles of 100.

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A Boy (a Bleeder) and a Bloody Revolution

E. Wayne Massey, M.D., and Janice Massey, M.D.

Hemophilia-induced femoral neuropathy led to leg paralysis and the paralysis of a government.

Tsarina Alexandra and Tsar Nicholas (figures 1 and 2, next page) were the last royal rulers of Russia. Their youngest child and only son, Alexis, was found to be afflicted with hemophilia. The retroperitoneal bleeding and femoral neuropathy caused by this disorder changed the course of Russian history.

In September 1912, the Russian royal family was vacationing in Poland, then under Russian rule, at Spala, the ancient hunting ground of kings. They were a cheerful, healthy family, completely oblivious of the turmoil brewing throughout Russia. With the Tsar and Tsarina were their five children: Olga, age 17, Tatiana, age 15, Marie, age 13, Anastasia, age 11, and Crown Prince Alexis, age 8, the Tsarevich and heir to the throne (figures 1 and 2).

The family was puzzled when Alexis began to appear ill over several days and finally was forced to take to his bed, pale and weak. No one could explain the malady. In an attempt to cheer up the young prince, Alexandra took him for a drive. At first Alexis seemed to respond, but after riding only a short distance he began to complain of pain in his left leg and lower abdomen. They turned back, but by then every slight jolt of the carriage caused the boy to cry out with pain.

Doctor Eugene Botkin, personal physician to the royal family, examined Alexis and found a large hematoma over the medial thigh and groin. The dreaded hemophilia was suspected, especially in light of the well-known history of the disease in the royal family.¹

The most eminent physicians of Russia were summoned

to the bedside of the young prince, including Doctors Rauchfess and Federov, both surgeons; Doctor Ostrogorsky, personal pediatrician to the royal children; and Doctor Vladimir Derevenko, personal physician to Crown Prince Alexis.² They examined Alexis again and again and spent hours in conference, searching for an effective remedy. None of their treatments worked. The hemorrhage continued until the thigh was drawn up against the chest with the hip flexed and externally rotated. The limb could not be extended because of the agony that ensued.

For eleven days the Tsarina did not leave the child's bedside. Alexis lay semiconscious and groaning, delirious when aroused, and screaming as the increasingly frequent spasms of pain racked his frail body. As the days wore on, the exhausted child's screams changed to the painful plea, "Mama, help me. Won't you help me?"³

The situation seemed hopeless. Both the child and his parents were sure that death was near. Little Alexis was heard to say, "When I am dead it will not hurt anymore, will it Mama?" And, "When I am dead, build me a little monument of stones in the woods."³

At first, the Tsar tried to conceal the crown prince's serious condition, but as death became more imminent and rumors more widespread, official bulletins were issued. At the news of Alexis's illness, the people of Russia, rich and poor alike, flocked to their churches to pray. Every church had special services. At the Cathedral of Our Lady of Kazan in St. Petersburg, the prayer vigil continued 24 hours a day. A tent was raised at Spala where there was no church, and Vassiliev, the priest, conducted a *Te Deum* daily.

Despite all of this, Alexis's condition still grew worse until one night he was so pale and weak that it appeared the end was near. The priest was summoned, and the child received the last sacrament. The notice went to St. Peters-

From the Department of Medicine, Division of Neurology, Duke University Medical Center, Durham 27710.

burg to prepare the final bulletin which would announce the death of the Tsarevich.

In the midst of preparations for the child's death, Tsarina Alexandra sent a telegram to a holy man, the starets Gregory Rasputin, a strange and mystical Siberian peasant reputed to be a man of God with powers of prophecy and healing (figure 3, facing page). The Tsarina entreated him to pray for Alexis's life. Rasputin immediately responded, "God has seen your tears and heard your prayers. Do not grieve. The Little One will not die. Do not allow the doctors to bother him too much."⁴ Two days later the hemorrhage had stopped, the pain had gone, and the fever had abated. Alexis slept peacefully for the first time in weeks. He was alive.

Alexandra became a devotee of Rasputin, certain that he had miraculously saved her son when everyone else had failed. From that time on, Rasputin's influence on the royal family, through the Tsarina, was firmly established.

Until his assassination on New Year's Eve, 1916, Rasputin wielded great power. By that time he had used his influence

to dictate appointments to every important government and church position in Russia. The most far-reaching consequence of his influence was in Tsar Nicholas's handling of domestic unrest. The Tsar was so mesmerized by Rasputin that he failed to respond to the terrible plight of the Russian people, setting the stage for the 1917 revolution that changed the course of history for Russia and for the world.

There is little doubt that Alexis suffered from the syndrome of femoral neuropathy due to retroperitoneal bleeding. The manifestations were classic: the flexed and externally rotated hip and the characteristic pain. All of this clearly indicated femoral nerve and psoas involvement. In fact, Alexis was in braces for almost a year before his hip was finally fully extended. In a picture taken shortly after the events at Spala, the flexion and external rotation of the left hip are evident, even in the braces — a clear consequence of the unchecked and prolonged bleeding (figure 4, facing page).

Rasputin's advice that the doctors leave the child alone



Figure 1 Tsarina Alexandra with Crown Prince Alexis.²



Figure 2. Tsar Nicholas holding Crown Prince Alexis.²

was medically sound. Once the doctors stopped their constant poking, probing and examination, a small but adequate clot could form without being dislodged.

Retroperitoneal bleeding with resultant femoral neuropathy is a consequence of anticoagulant therapy or of hemophilia. In this earlier era it was a matter of the gravest and most widespread political significance. It was an important factor in a turn of history that led eventually to the overthrow of the tsarist regime and to the ascendancy of communism in Russia. ■

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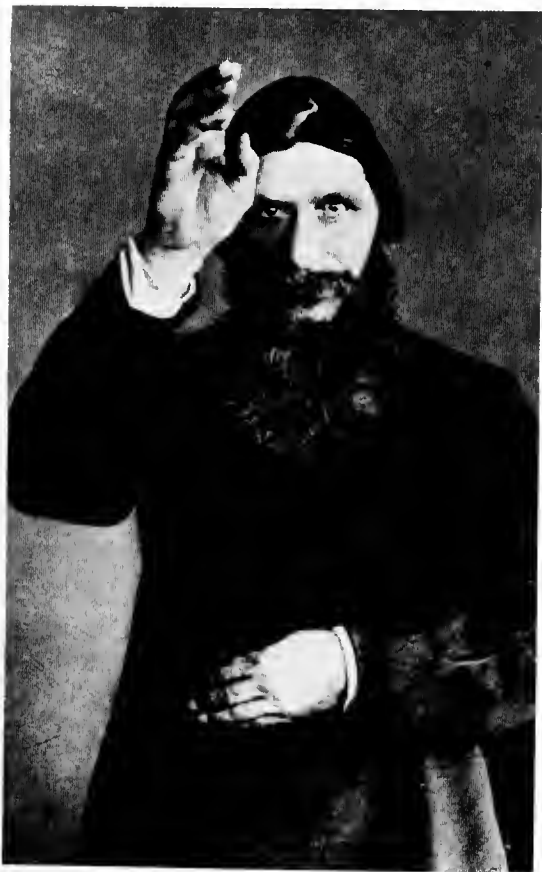


Figure 3. Gregory Rasputin.²



Figure 4. Tsarevich Alexis, after Spala. Left leg is held with hip flexed and externally rotated despite heavy metal brace.²



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*Caution: If perforation of the eardrum exists, specify Cortisporin Otic Suspension (this drug should be used with care in cases of perforated eardrum)

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For Patients

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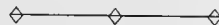
The Duke University School of Medicine

WILBURT C. DAVISON, M.D., A.M., F.A.C.P.,
Dean of the Medical Department of Duke University from 1927 to 1960

Editor's Note: Parents know that a child develops in an unpredictable way. A pediatrician is even more aware of this fact. Dean Davison in 1927 predicted how Duke would develop and published the prediction in *Transactions* of the North Carolina Medical Society. We reproduce the late dean's scenario with comments from three leading medical educators on what was fancy and what was reality.

Mr. President, Ladies and Gentlemen:
I wish to express my pleasure for this invitation to address you and for the opportunity to present the plans of the new medical school. There are at least six factors which are essential for the success of a medical school — the buildings, the staff, the students, the type of teaching, the service to the community and last, but not least, the cooperation of the members of the profession in the State. It is the great desire of everyone connected with Duke University so to carry out the plans for the first five of these essentials that the sixth one, namely, your cooperation, will be merited. We all wish you to regard this school as yours. Any suggestions which will increase the service of this school to the State will be more than welcomed, for service is to be the keystone of the arch

of this structure. These plans are in the tentative stage at present so I hope that you will not hesitate to point out anything which should be changed, for only by working together can this school fill the place which Mr. Duke intended.



(1) The *buildings* follow the same general arrangement as those at Nashville, Rochester, N.Y., and Chicago. The basic idea has been to group the various preclinical and clinical departments so that as much correlation as possible can be obtained. Physiology and biochemistry have an intimate relationship to internal medicine, and pathology is closely associated with surgery. The X-ray department has been placed as nearly as possible equidistant from the out-patient department, medicine and surgery. Another valuable feature is the proximity to the medical school of the University departments of the basic sciences, chemistry, biology and physics. It is expected that the buildings will be ready for occupancy before Sep-

Delivered at the 1927 Annual Session of the North Carolina Medical Society and published in its *Transactions* that year. Thanks go to Dr. J. B. (Ben) Warren of New Bern, who called this piece to our attention and was kind enough to send us a copy of it.

tember, 1929, and that first and third year classes can start at that time.



(2) The *staff* will be appointed by the Trustees as soon as the building program has made sufficient progress. In the recommendations for appointments, all of us here have an interest, for the personnel is of more importance than the stone and mortar. Information is now being collected in regard to the leaders of the various branches and suggestions are welcome. If most of the data obtained indicate that a certain man is the most desirable he will be asked to consider the appointment. If his answer is favorable, he will be invited to Durham to meet the officers of the University, the officers of the North Carolina Medical Society and other members of the profession in the State. We all feel it to be essential not only that the head of any department should be a leader in his own field, but also that he must be a man who will have the confidence and cooperation of the physicians and surgeons of the State. The heads of these departments will be on what is known as a "full time basis." They will be given adequate salaries and will not engage in private outside practice. There are many arguments in favor of and against this system, which I shall not enumerate, but shall merely mention two advantages; first, that the head of the department will be able to give his full time to the care of the patients in the hospital and to the training of students and post-graduates and, second, that he will be removed from competition with the members of the profession. There will probably be private patients whom you may wish to refer to the Professor of Medicine or Surgery for consultation or operation, and I hope that there will be, in order that this school can be of the greatest service, but all fees collected for private patients will go to the medical school and no private patient will be seen who is not referred by his or her own physician. It is hoped that physicians and surgeons in practice in the vicinity of Durham will accept part time appointments at the medical school and hospital, to assist in the care of patients and the teaching of students.



(3) The *students* will be limited to fifty in each class. It is possible and probable that for several years the classes may not be filled, for there will be rigid selection for entrance. This statement does not mean that a college degree and a vast number of hours will be required for admission, for I personally feel that two years of college, including one year of biology, one year of physics and two years of chemistry, are adequate preparation. It has been demonstrated that fewer failures occur in medical schools if the entering students are carefully selected on

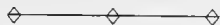
the basis of the quality of their preparation rather than on its quantity.¹ The actual requirements will not be decided until after the staff has been appointed but I trust that the basis of selection will be the candidate's intelligence and character instead of the length of his preparation. There is no doubt that a long preparation for the study of medicine has many advantages but the average age of twenty-six years at which the present medical students graduate is such a handicap to their post-graduate training as to require serious consideration to be directed toward condensation of their preliminary preparation. The same idea is behind the proposal that five terms of nine weeks will be given each year, commencing September first, with vacations of one week each in December, March and May, and of one month in August, and that the degree of M.D., will be granted after the satisfactory completion of fifteen terms. These may be taken consecutively (graduation in three calendar years), or four terms may be taken each year (graduation in four calendar years). Such a curriculum would in no way affect the courses at any other medical school. If the students who have received their first two years of training at Wake Forest or Chapel Hill wish to spend their clinical years at Durham, they can enter the eighth term, which would correspond to the third class, on June first or September first. It is impossible to state whether the faculty will eventually adopt this scheme but I feel that it will maintain the present standards of medical education and at the same time enable students to graduate at an earlier age than is possible at present.



(4) The type of *teaching* has not, of course, been outlined but it may not be out of place to mention some of the factors which must be considered. We hear frequent statements that the curriculum of this school is too theoretical while that of another one is splendidly practical. As a matter of fact, the methods taught in any medical school represent a compromise between the so-called theoretical ones which require a hospital for their accomplishment and the practical methods which can be carried out in general practice without elaborate equipment. The faculty of every medical school wishes to teach its students the most modern methods and also to instill into their minds the additional thought that these methods are not infallible and that better ones will probably be evolved. Everyone realizes that in medical school only the foundation of medical knowledge can be laid and the student must be given the training to enable him to keep constantly building and adding to the superstructure in accordance with medical progress. However, to produce this "open mind" toward new discoveries is naturally to weaken to a certain extent the students' confidence in our present practical remedies, and the knowledge that

many of the graduates of a school must practice medicine without modern hospital facilities has often caused more emphasis to be laid upon the practical medicine of today than upon the more theoretical possibilities of the future. The presence of so many splendid community hospitals in North and South Carolina will greatly simplify this problem and the medical students here can safely be taught the most modern methods, in addition to their fundamental training, for within a few years the physicians who practice in every county will probably have access to a hospital and its facilities. Formerly, the charge that a curriculum was too theoretical had some basis for the graduates of certain medical schools were often at a loss without hospital connections and as a result they congregated in cities instead of going into the country where they are needed and where their field for service is greater. Consequently, the community hospitals in North and South Carolina, in addition to the service which they are rendering in the care of the sick, are an important factor in medical education; first, by allowing the medical schools to modernize their teaching and second, by causing a redistribution of doctors from the cities, with one doctor to every 600 people, to the country districts with one doctor to every 1200.²

The modern medical curriculum is often blamed because more and more doctors are entering specialties and avoiding general practice. "General practice is doomed" is a common statement and the medical schools are held responsible. It is true that seventy-four per cent of the recent graduates of the medical schools throughout this country are specializing or planning to specialize in one or another branch,³ but is this the fault of the medical school curriculum or of natural economic causes? I personally think it is the latter. In this country the opportunities for service, reputation and monetary reward are at present unquestionably higher in the specialties than in general practice. Consequently the trend has been toward specialization, but even now the tide is turning. Twenty-two per cent of the 1915 graduates became otolaryngologists. At present that field is over-crowded and only fifteen per cent of the 1920 graduates are entering it.³ On the other hand the opportunities in pediatrics are increasing and we find that while only six per cent of the 1915 graduates in this country became pediatricians, eleven per cent of the 1920 classes are specializing in the diseases of children.³ Before the War in England the more ambitious men became specialists but during the last few years, because of the greater number of Harley Street consultants, more of the keener men are going into general practice where the rewards are now greater. There have been no changes in the medical school curriculum which are responsible for these trends; they are a response to economic conditions and I feel that we shall soon find in this country that the over-crowding of the specialties will cause an increase in the number of general practitioners — a consummation much to be desired.



(5) The medical school can be of *service to the community* in at least three ways: in the care of patients, in post-graduate instruction, and in assisting the community hospitals.

a) The physical facilities of the wards and out-patient department for the care of patients will be second to none and every effort will be made to provide the best of medical and nursing care, for this is the primary function of the hospital to which everything else is secondary. "Where will the patients for the new medical school come from?" is a frequent question. Many believe that a teaching hospital requires a huge metropolis. However, in 1913, Osler⁴ pointed out that a large population was not essential for a medical school and that Marburg in Germany, with twenty-three thousand people — half the size of Durham — maintained a medical school of the first rank. The population of Jena and Heidelberg are very similar to that of Durham and they certainly have no dearth of patients. This statement of Osler's is even more true today because of the tremendous increase in the number of automobiles. For medical schools in large cities, automobiles, by increasing the traffic congestion, have actually reduced the amount of territory from which patients may attend clinics. For instance in New York and Chicago nearly an hour is required to go from the center of the city to the medical schools. On the other hand, with the splendid roads in North Carolina, patients can be brought long distances by automobile in the same time and with more comfort and safety than is possible in traversing a large city. In addition to serving the 43,000 people of Durham, the wards and out-patient departments of the new medical school are thus readily accessible to the half million people who live within a fifty mile radius of the city. In addition, it is hoped that the medical school and hospital will be so conducted as to merit the confidence and cooperation of the staffs of the community hospitals throughout the two states so that patients will be referred to Durham. A large percentage of the most interesting and instructive cases in the hospital with which I am associated at present come from this area and I hope, without reflection upon that institution, that in the future they will prefer Durham to Baltimore.

b) The need for more provision for *post-graduate study* is very acute not only in this country but abroad. There are very few clinics to which a man can go, after he has been in practice several years, to obtain the additional training which he has found he needs. When insulin was first introduced, several institutions, through the kindness of Mr. John D. Rockefeller, Jr., established temporary post-graduate courses to train physicians in the use of this new remedy. The fact that so many doctors availed themselves of this opportunity is witness that

innumerable other courses are desired. It is the plan of the new medical school to attempt to fill this need. If a doctor in North or South Carolina wishes to spend a few days, weeks or months reviewing his knowledge of pediatrics, of obstetrics, of the treatment of syphilis, of studying the efficacy of liver diet in pernicious anemia, or if he has to do an unusual operation and wishes to refresh his memory of the anatomy involved, the facilities and equipment at Durham will be at his disposal. The service of a medical school should not be limited to the training of its own students and staff but should extend to giving the members of the profession of the state the benefit of everything it has. Training in preventive medicine and public health, not only for the students in the medical school, but also special work for those who wish to enter upon a career as health officers will be provided. Another of the functions of the medical school will be the lending of books and journals, for a complete medical library is contemplated. The library was actually started yesterday by the gift from Dr. John E. S. Davidson of Charlotte of a number of old books which he had collected. Old books are very valuable, for it is only by teaching students the history of medicine that they can gain a true conception of it and realize the progress which is constantly occurring.

c) The medical school can also be of service to the community hospitals. The pathological and bacteriological

departments can fill a need in the diagnosis of sections and cultures, the school of nursing can provide special training in obstetrics, pediatrics and other branches for the nurses of the smaller hospitals who desire it.

These are merely a few examples of the innumerable ways in which the school can be of service to the state, and in closing I should like to emphasize again the hope that you will make suggestions so that these plans will merit and receive your cooperation. The word Service is to be carved into the corner stone. ■

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Comment

WILLIAM G. ANLYAN, M.D.

Dr. Davison's remarks were made shortly after his appointment as Dean in 1927. At that point, his plans for Duke Medical School included: (1) recreating the Johns Hopkins model of full-time clinical faculty who would be consultants, but without any

significant private patients of their own; and (2) a flexible pre-medical college curriculum — not necessarily more than two years — based on his personal pre-medical-medical school experience which had been extraordinary in quality and unorthodox in quantity. He very correctly pointed out that people are more important than buildings. On the balance of producing generalists vs. specialists, he very carefully pointed out that the "market

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place" for practice was more important than the medical school curriculum — it is still equally true today.

What happened after his 1927 speech? Perhaps the most important uncontrollable event that shaped the future of Duke's clinical services was the Great Depression of 1929. When Dr. Davison recruited Dr. Deryl Hart in 1930 from Johns Hopkins to become the first Chairman of Surgery at Duke, it was apparent that there was not enough university money to recruit a high quality clinical faculty. Dr. Hart proposed and Dr. Davison accepted a plan to establish the Private Diagnostic Clinic as a geographic full-time clinical practice group within the medical faculty. A full professor earning \$5,000 a year would

receive one half of it from the institution and the other half from the pooled income of the group practice. In the ensuing 56 years the Private Diagnostic Clinic system has worked well to attract and sustain a top-notch clinical faculty as well as to contribute to the development of new programs and facilities for the entire Medical Center. Opening a new four-year medical school at the height of the Great Depression had the obvious long-range benefit of establishing a viable internal system of self-sustenance. We are indebted to the foresight and genius of Davison and Hart. Many other medical schools in the United States have adopted variants of the same plan. ■

Comment

JAMES F. GIFFORD, JR., Ph.D.

"The word Service is to be carved into the corner stone."

The craftsmanship that characterizes any speech reveals its purposes. Choosing "Service" as the theme for his announcement of plans for the Duke University School of Medicine allowed Dr. Davison to pursue several purposes simultaneously. He reminded his audience of James B. Duke's intention in giving; to aid Carolinians in meeting needs, improved health care first among them, otherwise beyond their means. He acknowledged the idealism of those among his listeners who had worked for decades to establish a clinical medical school in North Carolina. He worked to reduce the anxieties of those who feared that the new school would prove too competitive or too powerful a force for change within the context of medical practice in the region. Most important, he invited the physicians of the state to become involved with Duke immediately,

shaping it to their purposes even as they supported it by referring the patients that were essential to its future success. Service is at once an empowering and a constraining concept, and Davison drew upon both senses of the word.

In the crafting of his text Dr. Davison revealed his sensitivity to the mixed emotions of a group of professionals passing through a period of significant change. The emergence of hospitals as institutions essential to improving health care not only raised questions concerning what aspiring physicians should be taught but also caused concern among that segment of the profession who feared that they might be denied opportunity to practice in hospitals for want of proper training. Rising numbers of newly-trained specialists seemed to some to call the role of the general practitioner into question, and the majority of North Carolina physicians were general practitioners. Even among the most enthusiastic supporters of the new school, some questioned the wisdom

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or the desirability of placing the heads of medical departments on full-time salary. By raising these issues in the context of his announcement Dr. Davison allowed his audience to take his measure and, by so doing, created a basis both for personal communication and for professional cooperation.

Time and circumstance have changed the details of Davison's description of Duke. The original buildings, organized for internal efficiency, are now but a corner of a medical campus organized around the three functions of a modern medical center; patient care, teaching and research. The Depression doomed Davison's dream of establishing the faculty on a "full-time basis," but private practice by Duke faculty did not diminish the cooperation he sought with the medical profession of the state. As

training has improved, members of the medical profession no longer fear denial of access to hospitals; and Duke medical undergraduates, the number in each class now more than doubled, are taught, as Davison intended, by "the most modern methods." In 1987 new attention is being paid to the importance of small group teaching strategies, which Davison advocated. Most hospitals in North Carolina now do themselves most of the things Davison originally projected as services Duke might offer, and Duke now shares its teaching mission in the state with three other schools. These improvements in the quantity and quality of health care available to Carolinians are in part the product of those who shared Duke's originating mission, and bear witness to the vitality and validity of Dr. Davison's originating vision. ■

Comment

STUART BONDURANT, M.D.

Dean Davison embodied many superlatives, one of which was vision and another was purposeful adaptability. The 1927 paper on "The Duke University School of Medicine" illustrates both, for it contains the conceptual seeds from which Duke grew and which have powerfully influenced American medical education and medical practice, and it also contains evidences of Dean Davison's adaptability. Reading the paper for the first time, I was impressed anew by the scope of the vision which congenially blended science,

patient care, and community service with a central theme of education. It was refreshing to see again his clear and unambiguous views on pre-medical education (with which I agreed as a medical student in 1950 and disagree now), on the balance between theory and practice, and on the importance of general practice to which he recruited so enthusiastically throughout his career.

Dean Davison's vision, adumbrated in these pages, resulted in the first modern medical school in North Carolina. All three of the state's other medical schools, as well as the medical profession and the people of the state, have been immensely benefited by the products of this vision. We are also indebted to his remarkable effectiveness in bringing that vision into practice. ■

Dean, The School of Medicine, The University of North Carolina at Chapel Hill, Chapel Hill 27514.

Poetry

BILLY F. ANDREWS, M.D.

The Dean

In memory as in life the Dean, Wilburt C. Davison,
As teacher, physician, mentor, and friend my heart has won.
A giant among men in size and in mind
It is unlikely we again will see his kind.
In Duke Forest where a chapel stood alone,
He built a great medical center of the finest stone.
Destined to gain in medicine an outstanding fame
As Osler prophesied, medicine would never be the same.
Yet true greatness came in his service to children,
Through his magnetic, effervescent personality to stimulate men.
We stand in his shadow, are led by his light,
Our lives to enrichen and to become more bright.
His strength to protect and lead us in medicine's fight
To give to all patients what is best and right.
What a small way to pay him homage and to salute
With these few respectful and loving lines in tribute.

To My Good Doctor Willard C. Goley

What can be the doctor's greatest adversary?
Disease, suffering, death, and mortuary.
His greatest joy and goal is to prevent
Sorrow, pain, and loss of our bodies to rent.
To cure a few, to help many, to comfort all,
This is the good doctor's call.

This poem was written for Willard C. Goley, M.D., who was my family physician and first role model as a physician.

From Department of Pediatrics, University of Louisville School of Medicine, Louisville, KY 40292.

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Your challenge could be the Army Reserve unit near you. It's a unit that requires the services of surgeons.

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Two, the opportunity to explore other phases of medicine, to add a different kind of knowledge—the challenge of military health care. It's a flexibility which could prove to be both stimulating and rewarding, with the opportunity to participate in a variety of programs that can put you in contact with medical leaders from all over the country.

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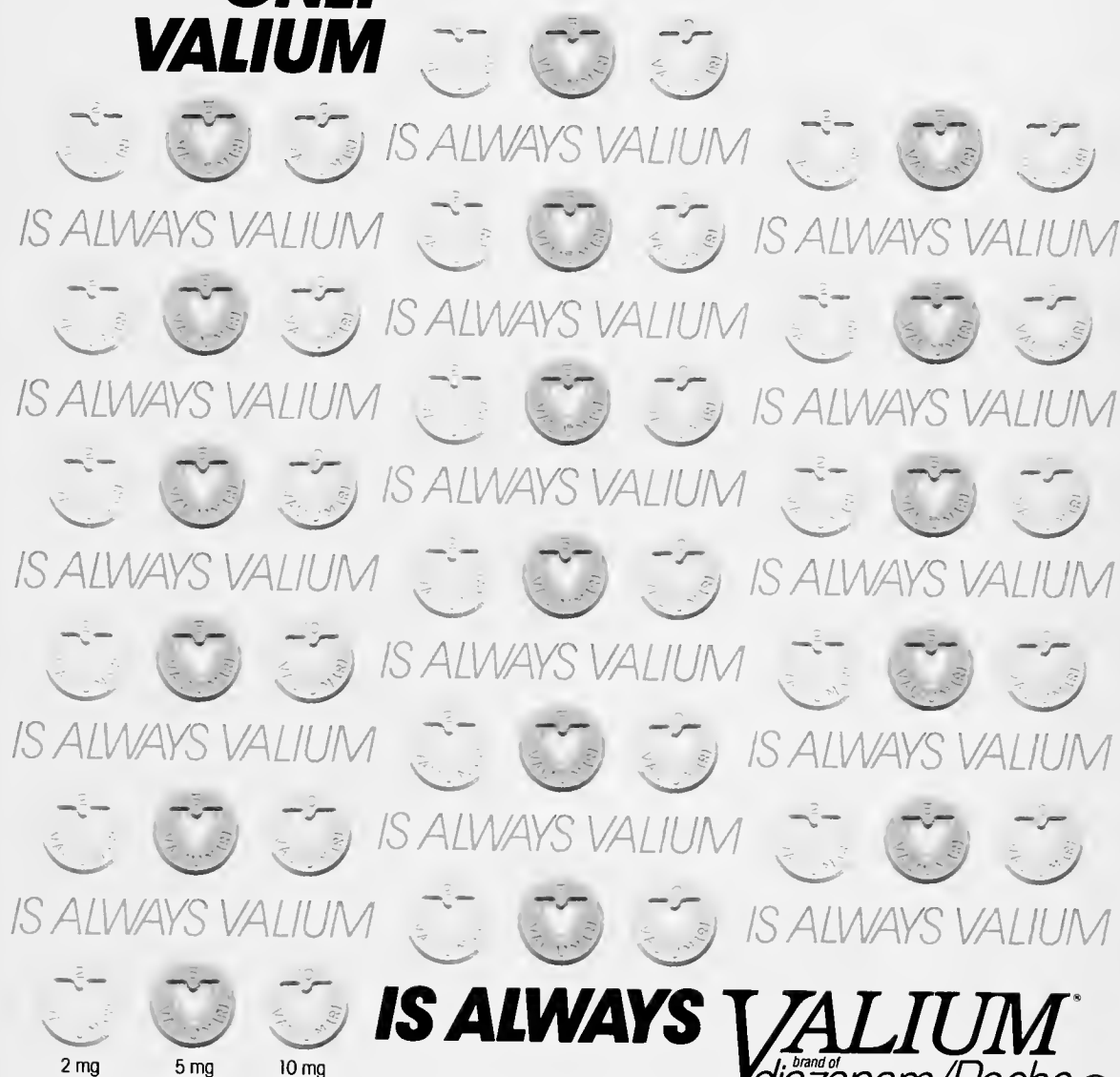
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OFFICIAL CALL HOUSE OF DELEGATES

HOUSE OF DELEGATES Meetings Scheduled

Notice to: Delegates, Alternate Delegates, Officials of the North Carolina Medical Society, and Presidents and Secretaries of county medical societies.

Sessions of the HOUSE OF DELEGATES will convene in the Cardinal Ballroom, Pinehurst Hotel, Pinehurst, North Carolina, at the following times:

Thursday, April 30, 1987 — 9:30 a.m. — Opening Session

Saturday, May 2, 1987 — 2:00 p.m. — Second Session

A member of the CREDENTIALS COMMITTEE will be present at the Desk in the West Lobby, Wednesday, April 29, 1987, 3:00 p.m. to 5:00 p.m., and Thursday, April 30, 1987, 8:30 a.m. to 10:00 a.m. to certify Delegates. Delegates are urged to bring their Credential Cards for presentation at the Registration Desk. Delegate Badges must be worn to be seated in the HOUSE OF DELEGATES.

REFERENCE COMMITTEE HEARINGS

Reference Committee hearings are scheduled to begin Thursday, April 30, 1987, at 2:00 p.m.

JOHN W. FOUST, M.D., President
HENRY J. CARR, JR., M.D., President-Elect
T. REGINALD HARRIS, M.D., Speaker
JOHN A. FOGG, M.D., Vice-Speaker
JOHN T. DEES, M.D., Secretary
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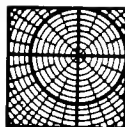
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Recent Changes in Physician-Hospital CEO Relationships

Thomas P. Weil, Ph.D.

The seeds of far-reaching changes in response to economic pressures can be found inside the health care industry.

Physician-hospital chief executive officer (CEO) relationships have undergone significant change in the past several years, primarily as a result of the passage of federal and state health care cost containment measures that have had these major impacts:

- Stabilized hospital Medicare expenditures by developing a prospective payment, diagnosis related grouping (DRG), price-oriented reimbursement methodology that provides incentives for ambulatory care services, and decreases inpatient average lengths of stay and ancillary utilization.
- Froze physician Medicare fees for nearly three years and placed them under federal controls beginning in 1987.
- Developed more regulations (e.g., peer review organizations), and yet encouraged more competition between physicians and hospitals, among hospitals, and among physicians — a situation that has in turn generated increased enrollment in alternate health care delivery systems such as health maintenance organizations (HMOs) and preferred provider organizations (PPOs).
- Modified some reimbursement incentives, with increasing limitations on third-party coverage, thereby sometimes changing how health care is delivered. This assumes there is agreement that the "money stream" has a direct impact on which, how, where, and to whom services are provided.
- Placed increased and in some cases different emphasis on ways of managing such health care cost containment measures as quality assurance, utilization review, case mix management, resources allocation, and productivity monitoring.
- Reduced many states' Medicaid expenditures by tightening eligibility requirements, narrowing the scope of benefits available, and implementing increasingly lower fees-rates relative to usual and customary community physician

charges, and, as a result, generated a rise in the number of persons who are uninsured.

This paper focuses on why the relationships between physicians and hospital CEOs are changing; why external, institutional, and office practice trends can be expected to exacerbate any organizational rifts in the next few years; and, finally, how hospital trustees can ensure the clinical and management leadership and the policy direction needed in this era when opportunities for major changes are still so readily available. The assumptions with which I begin this analysis are: (a) the physician and the hospital administrator are *not* natural adversaries, since each has a major dependency on the other; (b) new environmental forces are requiring doctors and hospital management to work more closely together; (c) power in many hospitals is shifting increasingly from the medical staff members to the CEO; and (d) most important of all, if there is understanding (not necessarily assent) of what is occurring around us in medical staff/administrator relationships, then institutions will expend their energies to implement the necessary changes.

External Factors

There are a large number of external factors that are accelerating the current unrest between physicians and hospital CEOs. Possibly the most quantifiable are the U.S. health expenditure's rise from 8.6% of the gross national product in 1975 to 10.6% in 1986, and hospitals' claim of a significant percentage of the nation's total health care dollars (44.9% in 1986).¹ This is in spite of the fact that the number of physicians in practice in the United States has increased from 377,000 in 1975 to nearly 450,000 in 1980. This number is projected to rise to nearly 600,000 by the end of this decade.² Considering that among those starting to practice in the 1990s will be the 16,400 admitted to medical school in 1986, the U.S. will have one actively practicing

From Bedford Health Associates, Inc., Management Consultants for Health and Hospital Services, Asheville 28801.

doctor per 400 persons within three years. One-third of the physicians practicing in 1990 will have completed their residency training in the 1980s. These quantitative data would suggest that the current oversupply of physicians will only intensify, and this finding has a number of implications.

There is increasing evidence that, beyond a minimum number, more physicians in a service area decrease both inpatient hospital utilization³ and the number of emergency room visits. The greater supply of qualified physician services will continue to decrease the number of inpatient admissions and days, forcing the hospital's management team to be more aggressive in marketing institution based services that are frequently in competition with the medical staff's office practice.

Many of the nation's teaching hospitals/medical schools are becoming more aggressive in establishing referral patterns as they are being adversely affected by the reductions in research and training grants, and as their former residents are providing more sophisticated procedures at community hospitals — procedures which were previously performed only at university referral centers. Meanwhile, managers of community hospitals are pressing their medical staffs for more paying admissions and seeking ways to minimize the number of referrals to teaching hospitals. The conflict between "town" and "gown" may well intensify in the next few years as both struggle to obtain a greater slice of a shrinking market.

Physicians and hospital administrators are often confused about how to react to the increasing competition between not-for-profit and investor-owned organizations. On one hand, most medical staff members are opposed to hospitals broadening their program or service base in ways that adversely affect the private practice of medicine. On the other hand, doctors are witnessing a sizeable and significant development of investor-owned primary, urgent, emergency, and ambulatory surgery centers, imaging centers, and other facilities where the ownership may be by physicians, another hospital, or outside entrepreneurs. In some cases these facilities have a direct impact on the doctor's office practice. The conflict becomes even more difficult to resolve if power brokers on the hospital's medical staff are prime leaders in the development of the investor-owned service without hospital participation, and if the venture is in direct competition with what the acute-care facility has traditionally provided (e.g., ambulatory surgery). The next few years may well witness the most difficult of times for hospital/medical staff relationships because of a decrease in the available health care dollar, coupled with fiscal constraints on acute-care institutions, and conflicts in determining equitable reimbursement for physician services. What could potentially be the most trying is the rolling of physicians' fees into the Medicare DRG rate,⁴ and an increasing number of administrators and doctors having to negotiate fee-for-service or capitation rates for providing specific care.

Internal Factors

The physician/hospital CEO relationship also needs to be further discussed in terms of a number of major internally-oriented changes that are occurring. Possibly the most striking changes in the past several years stem from the incentives inherent in most of the current third-party reimbursement plans. They have forced a reduction in the average length of hospital stay; they have encouraged the use of ambulatory rather than inpatient ancillary services, more critical evaluation of expensive equipment and supplies, and the development of clinical protocols by DRG to reduce the scope of routine orders by physicians on admission; and they have placed an emphasis on productivity, which in labor-intensive industries translates into a reduction in the number of full-time equivalent employees.

The declining average daily inpatient census could well result in friction between physicians and hospital CEOs in a number of other ways: (a) acute-care institutions will focus on increasing their admissions in reaction to the reduction of the average length of hospital stay, and many of the strategies used will be perceived as competition with individual physicians or other facilities; (b) hospitals are developing more sophisticated, integrated, and coordinated clinical-fiscal-management information systems that, as administrators choose doctors who are DRG "winners" or "losers," are perceived by physicians as starting to control the individual practice of medicine; (c) hospitals are reducing the number of full-time equivalent employees, when there is already some substance to the argument that patient care is adversely affected; (d) hospitals need to mobilize their resources so that they are both high tech and high touch, a difficult concept for many hospitals to implement; and (e) many new joint ventures will be consummated, but with the focus on who controls the enterprise and how the revenues are to be divided between the participating physicians and the hospital. Decreasing average daily census not only will intensify conflict between the medical staff and the hospital CEO, but also can result in further corporatization.

The traditional relationship between the medical staff leader and the hospital CEO may become more blurred because of the following factors: the greying of actual management philosophies between the not-for-profit and investor-owned endeavors; the decline in the number of free-standing institutions and the development of multi-hospital systems or, preferably, multi-level health care corporations; and institutional corporate restructuring and unbundling into holding companies with not-for-profit and for-profit subsidiaries. In fact, an increasing number of physicians are concerned about a facility or a specific clinical service being closed; about working with a hospital CEO who, more often now than a decade ago, is reporting to a senior corporate official many miles away; and about the not-for-profit hospital having to emulate some of the social values^{5,6} of the investor-owned facility in order to survive.

Although there is blurring today between the not-for-profit and investor-owned facilities in terms of the objective to improve the institution's bottom line, there is still concern over whether the mission of a hospital is to meet community health care needs or to maximize the stockholders' return on investment.⁷ There is increasing evidence that low-income and uninsured patients are having more difficulty obtaining care; there is already some rationing under way of expensive tertiary-type services; and, certainly, an increasing percentage of the cost of health care is being borne by the patient, whether in terms of dollars or of the family's increased assistance during the convalescent period because of a shorter hospital stay.

Physicians, like hospitals, are struggling to retain their traditional revenue stream, and are finding it increasingly difficult to maintain the same standard of living experienced by most doctors just a decade ago. Although in the 1971-1981 period there was a 12.0% per annum increase in per capita expenditure for physicians' services in the United States, and by the end of that period doctors had an average gross income of \$167,000 per year, the average net income from medical practice per physician (adjusted by the U.S. Department of Commerce fixed-weight price index for personal consumption expenditures) was marginally less in 1981 than in 1971 (table 1). Although there is public criticism that physicians' fees or their incomes are too high, the consumer price index (CPI) for physicians' services (deflated by the fixed-weight price index for personal con-

sumption expenditures) has increased only 1.0% per annum between 1971 and 1981. More recent data⁸ illustrate that the average practicing doctor has declining purchasing power, and that there is a sense among many physicians that a number of organizational-fiscal changes are already on their way, as so vividly publicized by the recent rise in malpractice premiums.

Who Is in Charge?

Much has been written in the past about the appropriate interaction of the governing board, medical staff, and management in the most effective and efficient operation of a hospital. The implementation of multi-level health care systems responsible for several hospitals in a region, and joint ventures between institutions and physicians, will result in analyses of where resources are and who obtains them in a shrinking marketplace. CEOs will be most vulnerable to the problems inherent in attempting to meet physicians' needs by expending resources while simultaneously creating a fiscal operating gain, thereby enjoying the confidence of the local governing board or central offices — a fine balance to maintain. To improve their relationships with physicians, health care CEOs will need to be particularly credible, enthusiastic, analytic, politically savvy, competent, and communicative, and yet remember that they are in an industry with a social responsibility to maintain the physical and

Table 1
Average Income Per Physician and Per Capita Expenditures for Physicians' Services, Nominal and Real, 1971 and 1981

Selected Variables	Year		Average Annual Percent Change
	1971	1981	
Per capita expenditures for physicians' services ¹	\$ 75	\$ 234	12.0%
Per capita expenditures for physicians' services deflated by the consumer price index for physicians' services	\$ 58	\$ 78	3.0
Average gross income per physician ²	\$74,197	\$167,000	8.5
Average gross income per physician deflated by the consumer price index for physicians' services	\$57,163	\$ 55,853	-0.2
Average total tax deductible professional expense per physician ²	\$28,919	\$ 74,000	9.9
Average total tax deductible professional expense per physician deflated by the fixed-weight price index for personal consumption expenditures ³	\$29,937	\$ 36,616	2.0
Average net income from medical practice per physician	\$45,278	\$ 93,000	7.5
Average net income from medical practice per physician deflated by the fixed-weight price index for personal consumption expenditures ³	\$46,872	\$ 46,017	-0.2
Consumer price index for physicians' services (1967 = 100.0)	129.8	299.0	8.7
Fixed-weight price index for personal consumption expenditures (1972 = 100.0) ³	96.6	202.1	7.7
Consumer Price Index for physicians' services deflated by fixed-weight price index for personal consumption expenditures ³	134.4	147.9	1.0

¹ Gibson RM and Waldo DR. National Health Expenditures, 1981, 1982: Health Care Financing Rev, September.

² American Medical Association, Profile of Medical Practice, 1981, and SMS Report, 1982: AMA Center for Health Policy Research.

³ The fixed-weight price index for personal consumption expenditures is reported in Bureau of Economic Analysis, Survey of Current Business, U.S. Department of Commerce.

Source: Freeland MS and Schendler CE, National health expenditures growth in the 1980s: an aging population, new technologies, and increasing competition. Health Care Financing Rev 1983;4:23.

mental well-being of the people their institutions serve.

Trustees, to be effective within the context of these physician-hospital CEO changes, will need to expend more effort in dialogue with medical staff and management representatives in evaluating how the facility's resources can best fit into the region's health care delivery system, and yet allow each of the parties to these discussions to remain fiscally viable. To have trustees dictating major policy decisions to the medical staff is no longer tolerable in this competitive and regulatory environment. Trustees with leadership skills and insight frequently have other professional or personal commitments that too often do not allow them the appreciable amount of time that it takes to work with a medical staff. One dinner meeting between key members of the governing board and medical staff on a crucial decision cannot bring about the rapport and joint effort that are so often required.

Governing boards, to shape the appropriate physician-CEO relationships of the future, will be focusing more on developing regional multi-level health care delivery systems and alternate prepaid health insurance programs (e.g., HMOs, PPOs, and independent practice associations). The current competitive environment has provided the opportunity to reshape the health care system with an emphasis on both regionalization and allowing employees-employers a greater selection of types of health insurance coverage.

Joint ventures between physicians and hospitals require trustees to consider doctors partners with the hospital. This kind of endeavor often requires trustees to make major decisions with counsel from the management team within a shorter time-frame than in the past. Since these undertakings are also frequently more complex in their organizational structure and financing, the board's final determination of whether or not to proceed is frequently made by a smaller number of doctors, trustees, and the management team.

Governing boards may have the most difficulty in resolving changes in the physician-hospital CEO relationship that concern some of the more clinical aspects of a hospital, such as quality assurance, the appropriate care of the uninsured, and needed justification for expending limited capital funds for new technology. There is in the larger hospitals a trend toward appointing a physician on a part- or full-time basis to serve as a kind of vice president of medical affairs, and this can be expected to occur more frequently in the future. Experience throughout the world has illustrated that as the health care system relies increasingly on public rather than private financing for its operating and capital revenues, physicians become a more integral part of the management team. It can be anticipated that for the types of decisions that have significant clinical overtones that may be more critical in the years to come, salaried physicians (maybe part-time while chief of staff) will be a prevalent pattern, the timetable dependent on the rolling of the physicians' fees into the hospital's DRG rates or some similar approach.

What we will see more often as a result of these physician-

hospital CEO changes is a utilization of the joint conference committee, or meetings of the executive committees of the governing board and medical staff, as possibly the real final sounding board for a proposal. In many ways, the final governing board action will be perfunctory. To make that type of organizational structure function, hospitals are going to need more joint trustee-MD committees that act as "working parties" (not to be considered a new management concept) to analyze in detail rather broad topics. The advantage of trustees and MDs working concurrently and jointly at the outset on a major decision is the combination of policy and clinical expertise that should allow the decision-making process to proceed more effectively and with greater precision.

The changes that are occurring in the health care system, and therefore in physician-hospital CEO relationships, not only provide an opportunity to organize the health care system with more multi-level integration and alternate health care plans attuned to the needs of the region, but also allow for governing board-medical staff-management teams to reevaluate their own decision-making processes. More intensive dialogue, more experience with joint ventures, and the appointment of physicians as members of the management team will be critical in meeting these changes in increasingly competitive and regulatory times; but probably the most promising technique is the establishment of more trustee-MD-management "working parties" that utilize the knowledge and skills of committee members to arrive at answers that meet the needs of the community and the health care providers, at the same time minimizing the self-interest of those involved in providing high-quality patient care to the region. ■

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My Kingdom for a Fix

"T's and Blues" — Was and Is

Ronald B. Mack, M.D.

Richard III has always been my favorite king. You say you don't have one and don't want one! Why not, it's a harmless indulgence and many of those historical figures have qualities that are worthy of emulation. For example, like me, Richard was short, tough, mean, ambitious and had the kind of face that did not attract groupies. I like that in a man, I can relate to that. He said, "That dogs bark at me as I halt by them . . . and therefore, since I cannot prove a lover to entertain these four well-spoken days, I am determined to prove a villain. . . ." At the end of his life, at the Battle of Bosworth Field, he is knocked off his horse in the middle of the battle, and instead of asking for a corpsman or medevac chopper he exclaims: "A horse! A horse! My kingdom for a horse." There are apparently some opiate junkies who would trade their kingdoms for some "T's and Blues."

To be honest, I thought we had seen the last of "T's and Blues" because of the recent formula change of pentazocine. But I am getting ahead of the story, more about the resurgence later.

"T's and Blues" refers to the combination of two drugs, pentazocine (Talwin) and tripeleminamine (Pyribenzamine); the latter is available in the form of *blue* tablets. Why would anyone want to take this mixture, is it for people with bad pain and a dripping nose from whatever, ragweed for instance? Nay, nay, it is a heroin-like substitute used by opiate addicted unfortunates who cannot score heroin because it is difficult to obtain or too expensive or who prefer this combination to heroin or any other opiate. "T's and Blues" are considerably cheaper to use than heroin.

Pentazocine (Talwin) was originally synthesized in an attempt to produce an analgesic that would be effective but lack abuse potential.² So much for good intentions!! The central nervous system (CNS) effects of this drug are similar to those of other morphine-like opioids, vis-a-vis sedation, analgesia and respiratory depression. It is well absorbed from the gastrointestinal tract as well as from subcutaneous and intramuscular sites. Peak plasma values occur 15 minutes to one hour after intramuscular administration and one

to three hours after oral administration. The first pass metabolism in the liver, when the drug is ingested, is formidable, and a bit less than 20% ultimately enters the systemic circulation. The plasma half-life is two to three hours. As you might imagine, pentazocine is metabolized in the liver and the metabolic products are excreted in the urine. There is the interesting finding that the rate of metabolism of this drug varies between individuals, accounting for the variability in analgesia. Speaking of analgesia, 30 to 60 mg of pentazocine parenterally is equivalent, generally, in analgesic affect, to 10 mg of morphine. This drug, in terms of its peak effect, is about one-fourth as potent orally as parenterally, and as an analgesic, only one-third as potent orally as parenterally.

Tripeleminamine is an H₁ blocking agent (AKA antihistamine) better known as pyribenzamine.³ This drug is an ethylenediamine type of antihistamine available in tablet and syrup form and is meant to be administered orally. When ingested, this drug is rapidly absorbed from the gastrointestinal tract with therapeutic effects beginning in 15-30 minutes and lasting four to six hours. It is widely distributed in the body including the central nervous system.

H₁ blockers, in general, share many pharmacologic properties. These include inhibiting the response of histamine, which can cause constriction of smooth muscle — e.g., gastrointestinal and respiratory systems and the vascular system — as well as antagonize the action of histamine that causes increased capillary permeability with subsequent formation of edema. H₁ blockers can stimulate and depress the CNS. The stimulation can be severe enough to cause convulsions, especially in young children. Depression of the CNS is a more typical reaction to these drugs even with therapeutic doses. The more outstanding features of antihistamines as a drug class is their ability to cause atropine-like *anticholinergic* effects such as dryness of the mouth, mydriasis, tachycardia, flushing of the skin, hallucinations, etc. Tripeleminamine, in all candor, is not exactly pristine in terms of drug abuse. In the 1960s this drug was mixed with paregoric, in times of heroin shortages, and was known as "blue velvet."

Now that we know what's in "T's and Blues" let's look

From the Department of Pediatrics, Bowman Gray School of Medicine, Wake Forest University, Winston-Salem 27103.

and see why anyone would want to combine these two drugs and then inject them to produce a "high." At this point it makes no sense and when we look into the problem further it will make even less sense. (This, by the way, is brought to you by a person whose idea of a "high" is a plate of aglio olió con linguine, with a glass of Chianti.) During the mid-1970s, apparently during a period of relative heroin drought, some "street chemists" found that this mild pain killer and this over-the-counter antihistamine could pack a wallop similar to "smack," horse, etc. Either of these drugs taken alone could produce sedation or anxiety, but taken together the combination produces a euphoric rush.

During this period in drug history, the mid 1970s, "street" heroin dropped in quality as well as quantity and this vacuum was partially filled by "T's and Blues." This potentially lethal combination began in the Midwest and spread from there to all parts of the country; it seems to be a purely American invention unlike our imported killers such as cocaine, etc. Even when heroin became more plentiful and of better quality this combination remained the drug of choice for many users. Why not, it was fairly easy to get, relatively cheap and the quality was usually a constant, unlike heroin whose concentration fluctuated widely.

The user mixed the drugs as follows: one or two 50 mg pentazocine tablets combined with one 50 mg tripeleminamine tablet. The tablets are crushed, dissolved in water, strained through cotton and injected intravenously. The effect is an immediate "rush" lasting five to ten minutes. The initial effects are soon followed by dysphoria, (a well of ill-being), so injections are repeated. After three or four such "shoot-ups" the rush may be followed by a longer-lasting feeling of well-being lasting one or two hours, which subsides over the succeeding two to four hours.⁴ Sounds fantastic, doesn't it? Seems like just the stuff to take before your spouse's high school reunion commences.

When the patient responds adversely to the "T's and Blues" infusion the results are fairly predictable, i.e. signs and symptoms of a narcotic overdose plus an antihistamine overdose. The clinical features that the patient experiences and that you may be called upon to treat include acute hypertension, tachycardia, arrhythmias, respiratory depression (usually less than from many of the narcotic analgesics), stupor, coma and seizures. You would expect miosis and, no surprise, it is typically present. Pentazocine overdose can produce the classic narcotic triad of coma, miosis and respiratory depression, but also can produce seizures. Meperidine (Demerol) and pentazocine (Talwin) are the two narcotics that are more likely to cause seizures in overdose. In addition to this clinical cluster of adverse features, "T's and Blues" can produce headache, blurred vision, dry mouth, vomiting, urinary retention and hallucinations. Long-term complications include superficial thrombophlebitis, skin abscesses, skin ulcerations, vasculitis, muscle fibrosis, talc granulomas and talc angiothrombosis (both of the latter from the cotton strainer, possibly), pulmonary hypertension and psychosis. It is considered bad form to use "T's and Blues"

during pregnancy; it can cause miscarriage and fetal addiction and newborn withdrawal states.

Woe is me, the Talwin Company must have cried (Winthrop Laboratories, a division of Sterling Drug, Inc.) — who needs this aggravation, this bad public relations. As reported in 1983 in the *Journal of the American Medical Association*, the company decided to reformulate pentazocine (Talwin) by adding naloxone to the compound. Naloxone (Narcan) is a narcotic antagonist that is inactive when taken by mouth and does not affect the safety and efficacy of pentazocine when taken orally as directed. The new formulation did not include pentazocine lactate, the legitimate injectable form of the drug.⁵

When the oral form of pentazocine was reformulated with naloxone, I breathed a sigh of relief; one more problem I would not have to struggle with. Those of us who felt that way were wrong. Cases of abuse of "T's and Blues" are still being reported and there are several reasons that can be offered for the failure of naloxone to completely eliminate the problem. Probably the major reason for this failure has to do with opioid receptor subtypes. (Are you sure you want to hear this?) Opioid drug and peptides bind to specific sites in the brain and other organs. The major categories of receptors, that are the best studied, appear to be:

1. *mu* (μ) receptors — associated with supraspinal anesthesia, respiratory depression, physical dependence and euphoria.
2. *kappa* (κ) receptors — associated with spinal anesthesia, miosis and sedation.
3. *sigma* (σ) receptors — associated with hallucinations, dysphoria, respiratory and vasomotor stimulation.

To further confuse us, pentazocine has both narcotic agonist and antagonist properties. Thus this drug has agonist effects at the kappa and sigma receptors but antagonist effects at the mu receptor. Naloxone, the narcotic antagonist, exerts its main effects on the mu receptor and may not antagonize the agonist actions of pentazocine at the kappa and mu receptors. If you don't quite grasp all this, never mind. The thing to remember is that a difference in receptor binding may account for the failure of the pentazocine-naloxone combination to block the effect of "T's and Blues." In other words, the unopposed action of pentazocine at the sigma receptor may be important in the drug's ability to alter mood and that's the name of the game — to produce, in the user, a mood-altering experience.

Other reasons given for the failure of pentazocine-naloxone reformulation to solve the "T's and Blues" abuse problem include: (1) naloxone has a very short half life; pentazocine's $T_{1/2}$ is longer — the user could wait till the naloxone effect wears off and then "Beam me up Scotty"; (2) tripeleminamine may have "high" producing qualities not related to its anticholinergic or antihistamine actions. It

may even be able to act at opioid receptors and may be only partially blocked by naloxone.⁶

For whatever reason, "T's and Blues" abuse is not to be spoken of in the past tense as yet. If you see a patient who you believe has overdosed on this combination, the treatment should include supporting the cardiac and respiratory functions of the patient of course. The antidote for pentazocine overdose is *naloxone* (adults: IV 0.4 to 2.0 mg initially; children: IV 0.1 mg/kg initially) repeated as needed. It is important to emphasize here that much higher than usual doses of naloxone may be needed to reverse the adverse effects of pentazocine. In general, large doses of naloxone have been given without evil effects. In severe cases *physostigmine* can be given to overcome the anticholinergic effects of tripeleminamine. Indications for physostigmine use include: severe hallucinations, hypertension, arrhythmias, convulsions (can also be caused by the pentazocine).

In the second half of the 19th Century Dr. William John Little described the disease we know as cerebral palsy; in fact, this physical condition has been referred to historically as "Little's Disease." Richard III's mother had a difficult labor, for the once and future king was in a breech presentation and had to be delivered by C-section. Dr. Little believed that Richard had cerebral palsy.⁷ In spite of his physical handicaps, Richard III was a formidable ruler and apparently had a fair amount of success with women. After he proposes to the Lady Anne (widow of the Prince of Wales) and she accepts, he exclaims:

Was ever woman in this humor wooed?
Was ever woman in this humor won?
I'll have her, but I will not keep her long.
What? I that killed her husband and his father
To take her in her heart's extremest hate,
With curses in her mouth, tears in her eyes . . .⁸

Did this dude have charisma or what? ■

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National Eye Care Project Has Toll-Free Helpline

Potentially blinding eye disease can be treated effectively if detected early, a fact that 4,755 elderly North Carolina residents have discovered through the National Eye Care Project (NECP).

Volunteer North Carolina ophthalmologists have uncovered 642 cases of cataracts, 59 cases of glaucoma, 138 cases of macular degeneration, and 26 cases of diabetic retinopathy, among elderly North Carolina residents who have called the toll-free Helpline — 1-800/222-eyes (3937) — to receive assistance through the NECP.

The public service, which offers medical eye care to the disadvantaged elderly at no out-of-pocket cost, is sponsored by the North Carolina Society of Ophthalmology and the Foundation of the American Academy of Ophthalmology.

The NECP is available to U.S. citizens or legal residents, age 65 or over, who are not currently under the care of an ophthalmologist, and who have not seen one within the past three years.

Since the North Carolina Helpline opened on May 19, more than 4,755 residents have called, resulting in more than 3,145 referrals of elderly patients to local volunteer eye physicians for medical examination and possible treatment for sight-threatening eye diseases.

More than 140,000 elderly Americans have called the toll-free helpline number — 1-800/222-eyes, since the project opened in

January. Amazingly, about 34% of those examined by ophthalmologists report that they had never before had a comprehensive medical eye examination. For another 20%, it had been more than five years since their last eye examination.

"We want elderly people to know that failing eyesight in their later years can be prevented or lessened through early diagnosis and treatment," said John H. Killian, M.D., president of the North Carolina Society of Ophthalmology. "We are now able to repair or even replace certain parts of the eye by using sophisticated surgical tools and important new drug therapies."

Periodic medical eye examinations are particularly important, said Dr. Killian, to detect potentially blinding eye disease such as glaucoma, which has no early warning signs. Nationwide, about 1,600 cases of glaucoma have been diagnosed and treated through the project.

After calling the toll-free Helpline, an elderly person will be mailed the name of a volunteer ophthalmologist who will treat the patient, regardless of his or her ability to pay, and who will accept (for this project) Medicare or insurance assignment as payment in full. If hospital care is needed, the ophthalmologist will work with a local hospital to make care available. Hospital charges, eyeglasses and prescription drugs are not paid through the program.

More than 7,000 ophthalmologists are participating in the NECP. The Helpline is open weekdays from 8 a.m. to 5 p.m. in all states (except Hawaii, 8 to 3).

Diuretic-Induced Edema

William B. Blythe, M.D.

I suspect that it comes as a surprise to most physicians that diuretic drugs, the very keystone of therapy for edema, may be, in themselves, the cause for edema — as well as confusion and frustration.

What is the clinical situation in which this oxymoronic phenomenon is likely to be seen? It is one that has been encountered many times over by many physicians — no matter what the specialty — who take care of women: the woman with what is referred to as idiopathic or cyclic edema.

A woman may come to her physician complaining of swelling or "puffiness" about the ankles, in the hands, around the eyes, in the abdomen, and various other parts of the body. More often than not, these symptoms occur in the days preceding menstrual bleeding.

Usually after the first visit, and, if not, almost certainly after the second or third, when the complaints have become increasingly serious, the doctor prescribes a diuretic drug with instructions that go something like this, "Ms. X, I can find no cause for your swelling; it's probably associated with your periods. I am giving you some water pills which you may take when you have the swelling."

The patient does this for a few times and then realizes that even more drug rids her of more swelling and discomfort and she feels much better: her ankles are thinner and there is no puffiness about the eyes and no abdominal bloating. Body weight is less. All is beautiful.

The bliss is short-lived. The patient realizes that when the diuretic drug is stopped, the swelling returns — and more emphatically.

The situation is now such that there are large weight gains and striking edema when the drug is not taken and marked weight loss occasioned by larger doses of drug.

The patient becomes obsessed with staying edema-free and more and more of her life is devoted to this. Her physician becomes uncertain about the nature of the edema and institutes an extensive and costly evaluation. He or she may even assign a more serious etiology — "heart failure" or "renal failure," for example — to the edema.

The patient changes physicians or becomes more and more surreptitious about her diuretic drugs. Potassium depletion, with its consequences, becomes manifest.

Confusion, dismay, and guilt are the governing factors, and the patient usually ends up with a psychiatrist, endocrinologist, cardiologist, nephrologist, or all four.

How can this concatenation be avoided? I am not certain that it can be all the time, but as is most often the case, an understanding of the pathophysiology will prevent — or minimize — the diagnostic and therapeutic abyss into which the uninformed may fall.

Professor H.E. de Wardener and his colleagues at the Charing Cross Hospital Medical School have led the way in enlightening us about this treacherous syndrome.

They have proposed that the edema in most patients with "idiopathic edema" is caused by the use of a diuretic drug. It is their thesis that whatever the initial reason for starting the drug, its continued use causes volume depletion which leads to increased plasma renin levels and thus to hyperaldosteronism. A vicious cycle now ensues; irregularity in the dose of diuretic drug may cause a sharp fall in urinary sodium excretion, a gain in weight, and the rapid onset of the characteristically uncomfortable edema. The presence of the edema prompts a quick return to the use of the drug, and the secondary hyperaldosteronism is enhanced.

Professor de Wardener points to an additional important factor. This has to do with carbohydrate and salt intake. Many patients confess that in attempting to control their weight, they sometimes vary considerably the amount of food they consume both when they are and when they are not taking diuretic drugs. They may "starve" themselves for several days and then eat voraciously. Sudden increases in carbohydrate and sodium intake after fasting can cause retention of sodium and water.

It is de Wardener's suggestion that the syndrome of idiopathic edema did not exist before oral diuretic drugs were available. Although not all experts are as convinced of the etiologic role for diuretic drugs, all are convinced that the drugs are the most important factor in exacerbating the manifestations, and prolonging the course, of idiopathic edema.

How then should the physician approach the patient with idiopathic edema?

First, there must be a keen awareness of its existence; second, early in the relationship with the patient, disorders of the heart, liver, and kidneys should be ruled out as the cause for the edema; third, small doses of diuretic drugs should be prescribed only when absolutely necessary, and

From Department of Medicine, The University of North Carolina, North Carolina School of Medicine, Chapel Hill 27514.

the patient must be convinced that they should be taken regularly and not intermittently; and last, the physician must be aware that if the edema becomes strikingly worse, the

patient has entered the vicious cycle that I have described. Treating these patients is a challenge and treating them successfully is quite satisfying to patient and physician alike.

1987 National Psychology Awards for Excellence in the Media

The American Psychological Association and the American Psychological Foundation announce the 1987 National Psychology Awards for Excellence in the Media.

The purpose of the awards are to recognize and encourage outstanding, accurate coverage which increases public understanding of psychology. Winners in each of six categories will receive a \$1,000 cash award, a certificate, and an invitation to attend the 95th Annual Convention of the American Psychological Association in New York City.

Categories are: newspaper reporting; television/film (news/documentary); magazine articles; radio programs; television (drama/entertainment); and books/monographs.

Entry deadline is April 15, 1987.

For further information, write to: National Media Awards, Public Affairs Office, American Psychological Association, 1200 Seventeenth St., N.W., Washington, DC 20036. 202/955-7710.

Dx: recurrent herpes labialis

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ZANTAC® 150 h.s.

ranitidine HCl/Glaxo 150 mg tablets

EFFECTIVE MAINTENANCE THERAPY

for healed duodenal ulcer patients

CONFIRMED

In two randomized, double-blind, and well-controlled clinical trials, ZANTAC 150 mg h.s. significantly superior to cimetidine 400 mg h.s. for maintenance therapy in healed duodenal ulcers.

Percent of patients with observed duodenal ulcer recurrence

		0-4 months	0-8 months	0-12 months	No. patients
USA ¹	ranitidine 150 mg h.s.	9%	14%*	16%†	60
	cimetidine 400 mg h.s.	23%	34%	43%	66
UK, Ireland, Australia ²	ranitidine 150 mg h.s.	8%‡	14%‡	23%‡	243
	cimetidine 400 mg h.s.	21%	34%	37%	241

*p=0.02

†p=0.01

‡p<0.004

%=life-table estimates

All patients were permitted prn antacids for relief of pain.

These two trials used the currently recommended dosing regimen of cimetidine (400 mg h.s.) and ranitidine (150 mg h.s.). A comparison of other dosing regimens has not been studied.

The studied dosing regimens are not equivalent with respect to the degree and duration of acid suppression or suppression of nocturnal acid.

The superiority of ranitidine over cimetidine in these trials indicates that the dosing regimen currently recommended for cimetidine is less likely to be as successful in maintenance therapy.

Convenient once-a-night dose with a

low incidence of side effects³

Headache, sometimes severe, seems to be related to ranitidine administration. Other side effects have been reported; for a complete listing, see the ADVERSE REACTIONS section in the Brief Summary.

No significant interference with the hepatic cytochrome

P-450 enzyme system at recommended doses

ZANTAC 150 mg has no significant drug interactions with theophylline, phenytoin, or warfarin. The bioavailability of certain medications whose absorption is dependent on a low gastric pH may be altered when ZANTAC or other medications that decrease gastric acidity are administered.

Zantac[®] 150
ranitidine HCl/Glaxo 150 mg tablets

One tablet at bedtime
for maintenance

See next page for references and
Brief Summary of Product Information.

Glaxo /  **ROCHE**

CONFIRMED

Zantac 150

ranitidine HCl/Glaxo 150 mg tablets

One tablet at bedtime for maintenance therapy
in healed duodenal ulcer patients

References:

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3. Data available on request, Glaxo Inc.

ZANTAC[®] 150 Tablets
(ranitidine hydrochloride)
ZANTAC[®] 300 Tablets
(ranitidine hydrochloride)

BRIEF SUMMARY OF PRODUCT INFORMATION

The following is a brief summary only. Before prescribing, see complete prescribing information in ZANTAC[®] product labeling.

INDICATIONS AND USAGE: ZANTAC[®] is indicated in:

1. Short-term treatment of active duodenal ulcer. Most patients heal within four weeks.
2. Maintenance therapy for duodenal ulcer patients at reduced dosage after healing of acute ulcers.
3. The treatment of pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome and systemic mastocytosis).
4. Short-term treatment of active, benign gastric ulcer. Most patients heal within six weeks and the usefulness of further treatment has not been demonstrated.
5. Treatment of gastroesophageal reflux disease (GERD). Symptomatic relief commonly occurs within one or two weeks after starting therapy and is maintained throughout a six week course of therapy.

In active duodenal ulcer, active, benign gastric ulcer, hypersecretory states, and GERD, concomitant antacids should be given as needed for relief of pain.

CONTRAINDICATIONS: ZANTAC[®] is contraindicated for patients known to have hypersensitivity to the drug.

PRECAUTIONS: Symptomatic response to ZANTAC[®] therapy does not preclude the presence of gastric malignancy.

Since ZANTAC is excreted primarily by the kidney, dosage should be adjusted in patients with impaired renal function (see **DOSE AND ADMINISTRATION**). Caution should be observed in patients with hepatic dysfunction since ZANTAC is metabolized in the liver.

False positive tests for urine protein with Multistix[®] may occur during ZANTAC therapy, and therefore testing with sulfosalicylic acid is recommended.

Although recommended doses of ZANTAC do not inhibit the action of cytochrome P-450 enzymes in the liver, there have been isolated reports of drug interactions which suggest that ZANTAC may affect the bioavailability of certain drugs by some mechanism as yet unidentified (eg, a pH-dependent effect on absorption or a change in volume of distribution).

Lack of experience to date precludes recommending ZANTAC for use in children or pregnant patients. Since ZANTAC is secreted in human milk, caution should be exercised when administered to a nursing mother.

ADVERSE REACTIONS: Headache, sometimes severe, seems to be related to ZANTAC[®] administration. Constipation, diarrhea, nausea/vomiting, and abdominal discomfort/pain have been reported. There have been rare reports of malaise, dizziness, somnolence, insomnia, vertigo, tachycardia, bradycardia, premature ventricular beats, and arthralgias. Rare cases of reversible mental confusion, agitation, depression, and hallucinations have been reported, predominantly in severely ill elderly patients.

In normal volunteers, SGPT values were increased to at least

twice the pretreatment levels in 6 of 12 subjects receiving 100 mg qid IV for seven days, and in 4 of 24 subjects receiving 50 mg qid for five days. With oral administration there have been occasional reports of reversible hepatitis, hepatocellular or hepatocanalicular or mixed, with or without jaundice.

There have been rare reports of reversible leukopenia, granulocytopenia, thrombocytopenia, and pancytopenia.

Although controlled studies have shown no antiandrogenic activity, occasional cases of gynecomastia, impotence, and loss of libido have been reported in male patients receiving ZANTAC, but the incidence did not differ from that in the general population.

Incidents of rash, including rare cases suggestive of mild erythema multiforme, and, rarely, alopecia, have been reported, as well as rare cases of hypersensitivity reactions (eg, bronchospasm, fever, rash, eosinophilia) and small increases in serum creatinine.

OVERDOSEAGE: Information concerning possible overdose and its treatment appears in the full prescribing information.

DOSE AND ADMINISTRATION: Active Duodenal Ulcer: The current recommended adult oral dosage is 150 mg twice daily. An alternate dosage of 300 mg once daily at bedtime can be used for patients in whom dosing convenience is important. The advantages of one treatment regimen compared to the other in a particular patient population have yet to be demonstrated.

Maintenance Therapy: The current recommended adult oral dosage is 150 mg at bedtime.

Pathological Hypersecretory Conditions (such as Zollinger-Ellison Syndrome): The current recommended adult oral dosage is 150 mg twice a day. In some patients it may be necessary to administer ZANTAC 150-mg doses more frequently. Doses should be adjusted to individual patient needs, and should continue as long as clinically indicated. Doses up to 6 g/day have been employed in patients with severe disease.

Benign Gastric Ulcer: The current recommended adult oral dosage is 150 mg twice a day.

GERD: The current recommended adult oral dosage is 150 mg twice a day.

Dosage Adjustment for Patients with Impaired Renal Function: On the basis of experience with a group of subjects with severely impaired renal function treated with ZANTAC, the recommended dosage in patients with a creatinine clearance less than 50 ml/min is 150 mg every 24 hours. Should the patient's condition require, the frequency of dosing may be increased to every 12 hours or even further with caution. Hemodialysis reduces the level of circulating ranitidine. Ideally, the dosage schedule should be adjusted so that the timing of a scheduled dose coincides with the end of hemodialysis.

HOW SUPPLIED: ZANTAC[®] 300 Tablets (ranitidine hydrochloride equivalent to 300 mg of ranitidine) are yellow, capsule-shaped tablets embossed with "ZANTAC 300" on one side and "Glaxo" on the other. They are available in bottles of 30 (NDC 0173-0393-40) and unit dose packs of 100 tablets (NDC 0173-0393-47).

ZANTAC[®] 150 Tablets (ranitidine hydrochloride equivalent to 150 mg of ranitidine) are white tablets embossed with "ZANTAC 150" on one side and "Glaxo" on the other. They are available in bottles of 60 tablets (NDC 0173-0344-42) and unit dose packs of 100 tablets (NDC 0173-0344-47).

Store between 15° and 30° C (59° and 86° F) in a dry place. Protect from light. Replace cap securely after each opening.

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Glaxo

Glaxo Inc
Research Triangle Park, NC 27709

Digibind®

A New Frontier in the Treatment of Digitalis Toxicity

Brad Stolshek, Pharm. D.

Digoxin immune Fab (ovine) — Digibind® — is a newly marketed orphan drug from Burroughs Wellcome, indicated for the treatment of life-threatening digoxin toxicity. Digoxin antibodies were first produced in 1967 and have evolved with antibody research throughout the 1970s.¹

To produce the antibody, digoxin is coupled to an immunogenic protein carrier (human serum albumin) which is injected into sheep. After three months of incubation, the antiserum is collected, a crude IgG fraction is isolated, and the Fab fragment is cleaved by treatment with papain.² Fab fragments offer advantages over IgG molecules in that they are smaller (50,000 daltons vs 150,000 daltons), distribute more rapidly into tissue, have a larger volume of distribution, are excreted faster, and are less immunogenic.³

Digoxin Mechanism

Digoxin has high affinity and high specificity for the NaK-ATPase inhibitory site. The inhibition of the NaK-ATPase site results in the intracellular Na⁺ concentration rising and leads to increased intracellular Ca⁺ providing a positive inotropic effect. The entire mechanism of digitalis toxicity has yet to be determined. Many hypotheses involving the NaK-ATPase receptor have been proposed without conclusive evidence.^{4,5} NaK-ATPase inhibition results in prolongation of the action potential plateau. It is also thought that digitalis possesses a cholinergic property responsible for its AV node blocking properties; however, the mechanism of action for this effect is not well elucidated. Extracellular potassium increases in patients with digitalis toxicity because the NaK-ATPase is ineffective in exchanging sodium and potassium.

Treatment of Digoxin Toxicity

The treatment of digoxin toxicity has been revolutionized

From Drug Information Service, Department of Pharmacy, Duke University Medical Center, Box 3089, Durham 27710.

by the use of digoxin immune Fab. Digoxin immune Fab binds digoxin to form an inactive drug-antibody complex. This binding occurs readily because the antibody-drug affinity is greater than drug-receptor affinity. A shift of the equilibrium away from the receptor then occurs, and the drug-antibody complex is cleared by the kidney with an elimination half-life of 16 to 20 hours in patients with good renal function.⁶ Half-life in patients with renal failure has not been reported, but drug-antibody binding effectiveness and safety are similar in these patients without altering the dose.⁶

The manufacturer has reports of over 200 patients having been treated with Digibind® to date. Data on file at the company on 114 patients ranging in age from one day to 85 years reports the experience for digoxin immune Fab use. Ninety-four patients had resolution of toxicity following treatment; however, one patient exhibiting only a partial response died due to inadequate antibody availability in the hospital.

The reasons for toxicity included accidental ingestions, suicide attempts, and developments during the routine course of therapy (more than 50%). Treated patients had serum digoxin levels ranging from 1.2 to 100 ng/ml with 75% of the levels > 5 ng/ml. Of the remaining patients, nine were excluded due to inadequate dose, incorrect diagnosis, or agonal rhythm at the time of dosing. In four patients, the data are still being collected. Seven non-response cases were described as: multiple drug overdose (2); severe heart disease with questionable diagnosis of digitalis toxicity (3); severe electrolyte disturbances (1); and no response (1). Adverse reactions to the drug have been minimal. There have been three cases of allergic reactions: one case of erythema at the site of injection; one case of facial swelling and hives occurring halfway through the 30-minute infusion (infusion was stopped); and one case of rash and urticaria occurring one day after the Digibind® infusion was completed (cause not established). No incidence of anaphylaxis, serum sickness, or febrile reaction has occurred.

Repeat administration to treat a second digitalis toxicity

in a patient has not occurred, but has the potential for causing an immunologic reaction. Decreased ventricular function and exacerbation of heart failure is always a consideration when withdrawing digitalis support. In an earlier published study of 63 patients, six showed a decline in cardiac function within a day of digoxin immune Fab administration; however, most patients noted improvements in their hemodynamic states with resolution of their arrhythmias.⁶ Serum potassium levels often drop dramatically within one to five hours following administration of digoxin immune Fab. This is consistent with reversal of inhibition of NaK-ATPase and K⁺ returning into the cells. Serial serum potassium concentrations should be monitored starting one to two hours after the administration of digoxin immune Fab.

Administration of Digoxin Immune Fab

The dose used to treat toxicity has ranged from 4 to 1600 mg. Suicide attempts require the highest doses of digoxin immune Fab. Dosage calculations are performed in several ways. In a massive ingestion, the total amount of digoxin ingested multiplied by 0.8 (bioavailability of digoxin) will estimate how much digoxin is absorbed. If it is believed that all of the digoxin has been absorbed (complete absorption takes six to eight hours), or if a patient has been on a stable dose of digoxin, then a drug concentration can be used. Table 1 shows calculation of total body digoxin load in milligrams. Using equimolar doses of digoxin immune Fab to digoxin, 40 mg (or one vial) of immune Fab should be administered for every 0.6 mg of total body digoxin. These calculations should be rounded up to the nearest vial. With digitoxin, the bioavailability is 100% and the volume of distribution is 0.56 l/kg.⁷ Digoxin immune Fab has been administered as an intravenous slow infusion of two hours' duration in early stages of the clinical trials. Recently, infusion times have been decreased to 15-30 minutes; bolus administration is used with ongoing or imminent cardiac arrest. The manufacturer recommends filtering the solution

upon administration. Initial clinical response can be seen within 30 minutes of termination of the infusion. Complete resolution of both cardiac and noncardiac manifestations of digoxin toxicity are usually observed by three to four hours post infusion.^{6,8}

Patients who require digoxin for their heart conditions must wait until the digoxin immune Fab is cleared from the body before redigitalization can occur. When digoxin is administered before total unbound antibody is cleared, the new digoxin will bind, thus lowering expected serum concentrations. Elimination of the antibody-digoxin complex in patients with normal renal function occurs in two to three days, whereas in patients with poor renal function, elimination is believed to be prolonged.^{6,8}

Availability of Digibind[®]

Burroughs Wellcome has a goal of distributing Digibind[®] to 130 strategic centers in the United States so that it can be obtained within one hour of a phone call. The company has provided a toll-free line (800/672-7223 in NC) for information on obtaining Digibind[®]. The wholesale cost of a single vial of Digibind[®] is \$145.70. Hospitals in North Carolina acting as regional centers are NC Memorial in Chapel Hill, Charlotte Memorial, Duke University in Durham, Onslow Memorial in Jacksonville, and Baptist in Winston-Salem.

Duke has been one of 13 centers selected to conduct experimental trials using digoxin immune Fab. Robert Califf, M.D., and Gary Dunham, R.Ph., have treated 19 of the 114 patients reported by the manufacturer. In addition, they are involved in the post-marketing surveillance program that is monitoring patients receiving Digibind[®]. These investigators may be contacted 24 hours a day by phone or beeper for answering questions regarding dosing and administration of this agent.

Digoxin immune Fab (ovine) — Digibind[®] — should be considered first-line therapy for digitalis toxicity when hyperkalemia and life-threatening arrhythmias are present. When digitalis toxicity is not life-threatening, other forms

Table 1

A. Calculation of total body digoxin (digitoxin)

1. Acute ingestion method

Number of mg ingested \times 0.8 (1.0 for digitoxin) = mg absorbed (total body digoxin/digitoxin)

2. Serum drug level method

$$\frac{\text{Level (ng/ml)} \times 5.6 \text{ l/kg} \times \text{body weight (kg)}}{1000} = \text{Total body digoxin (mg)}$$

(Volume of distribution — digitoxin = 0.56 l/kg)

B. Calculation of amount of digibind to use

$$\frac{\text{Total body digoxin (mg)}}{0.6} = \text{Number of vials of digibind}$$

of management should be considered. Although the antibody has the potential to be immunogenic, side effects have not been significant. ■

References

1 Butler VP, et al. *Proc Nat Acad Sci USA*. 1976;57:71-8.

2 Smith TW, et al. *N Engl J Med* 1976;797-800.

3 Cole PL, et al. *Drug Intell Clin Pharm* 1986;20:267-70.

4 Hoffman BF, et al. *Goodman and Gilman*, 7th ed. 1985.

5 Smith TW, et al. *Prog Cardiol Dis* 1984;26:495-540.

6 Wenger TL, et al. *J Am Coll Cardiol* 1985;5:118A-23A.

7 Package insert. Burroughs Wellcome Co., Research Triangle Park, N.C., 1986.

8 Data on file. Burroughs Wellcome Co., Research Triangle Park, N.C., 1986.

Charlotte Resident Named Trustee of AARP Andrus Foundation

Dr. Monroe Gilmour of Charlotte, North Carolina, has been appointed to the Board of Trustees of the Andrus Foundation of the American Association of Retired Persons (AARP), it was announced here today by Dr. Kenneth Cook, the Foundation Administrator. Dr. Gilmour will serve a six-year term.

Trustees of the AARP Andrus Foundation administer funding for grants of up to \$50,000 in gerontological research covering the social, behavioral and health aspect of aging. The research is aimed at improving the quality of life for older Americans.

Researchers affiliated with universities in North Carolina have received numerous grants from the Foundation. They include Duke, Wake forest, North Carolina State and East Carolina universities and the University of North Carolina at Greensboro.

Dr. Gilmour is a member of the AARP Board of Directors and serves as consumer Representative on the Board of Medical Review of North Carolina, Inc. Previously, he was National Secretary for

the association and served on the board of the AARP Foundation.

A graduate of Harvard University Medical School, Dr. Gilmour established his practice in Charlotte in 1940. In 1947, he founded the Durwood Medical Clinic, where he was senior staff member until his retirement in 1980.

He is Chairman of the North Carolina Medical Society committee on Aging and has been elected to the North Carolina Institute of Medicine. Dr. Gilmour has written a number of articles for medical journals, and is listed in the 1960 *Who's Who in America*.

Dr. Gilmour is Vice chairman of the Charlotte Treatment Center and immediate Past President of the United Way of Mecklenburg and Union Counties. He was president of the North Carolina Society of Internal Medicine, is a Fellow and past governor for North Carolina of the American College of Physicians, and is a Fellow of the American College of Cardiology.

Established in 1973 as a living memorial to AARP's founder, Dr. Ethel Percy Andrus, the Foundation has awarded 295 grants totalling \$10,315,406 to 124 colleges and universities. Most of the money comes from AARP members through donations they add to membership renewals.

With 24 million members, AARP is the nation's largest organization of Americans age 50 and older.

Headquartered in Washington, D.C., the nonprofit, nonpartisan organization offers a wide range of membership benefits, legislative representation at federal and state levels, and educational and community service programs carried out through a national network of volunteers and local chapters.

The association also offers a variety of educational and advocacy programs for older workers who make up one-fourth of AARP's total membership.



Dr. Monroe Gilmour

An Elderly Patient and a Geriatric Educator

Noel David List, M.D.

An elderly gentleman provided an extended education in the spectrum of problems facing the physician who treats geriatric patients.

Ben was already 86 years old when I met him. I was one week into directing a geriatric program and he was about to enter the world of long-term care. We talked for a while. He asked me if I would become his physician.

Ben's usual physician didn't go to nursing homes, and, Ben felt, never took the time to talk, or more importantly, to listen; when his physician did talk, it was to Ben's family about how to solve Ben's problems.

I found an articulate, well educated, kind and caring gentleman who was now starting out on his own in a nursing home with fears and concerns about social losses and the changes in his environment. Ben was about to leave his home and possessions of a lifetime. While many of his older friends had died, he still had many of all ages in his neighborhood. The world of the nursing home, which he had visited, presented an alarming contrast: it was regimented, it had many sick and demented patients, and in every way, he felt, it was depressing. He was also concerned about his own health.

Ben's statements were tempered by wisdom and wit. His first request was for help in finding a woman companion; although this was said as an opening ploy for conversation, the underlying loneliness and feeling of isolation were evident.

Ben had grown up in eastern Europe but decided to emigrate to the United States. Over the years he had built a successful furniture business, married, and had children, grandchildren and three great-grandchildren. His most difficult time followed the death of his wife about a year before we met.

Ben's family felt that he had no one to be with after his wife's death, and so they wanted to place him in the nursing home. He would frequently talk about his wife and the "way

it feels" to be without her. It was an open wound of loneliness that never healed. They had 62 years together. She took good care of him.

Ben had given over his business to the children at age 70. Over the years, Ben and his wife had put their money into funds to support the family, and with Ben's power of attorney the family now managed everything. He shuddered at the fact that he controlled nothing. He had a wonderful house with some land in a part of the city that was growing rapidly around him. Ben said he wanted to be independent, to work and to be useful. His children were afraid to leave him alone, but were unable for various reasons to come and visit.

One of Ben's sons had brought him to the nursing home and told me about his father. Later, when I was examining Ben, I was taken aback by his comment that he had appreciated hearing his son say something nice about him; he only wished the young man would say something nice to him once in a while.

Over the years in the nursing home, Ben tried to make a life. The place never became a home. He never felt much like eating. He didn't think it was depression, but just not having somebody to cook and to eat with. He would explain that he wanted to help people, to be with people, feel useful; he felt he could be happy then. He felt fortunate in that he didn't have much in the way of disease. He had an early cataract. He took "some heart medications." He described the swelling in his feet that had occurred some years ago, for which he had been placed on these "medications." Many of his friends were on more medication than he could count on both hands. He had told his other physician he didn't want medicines, especially ones to help him sleep. He was not sick, he was just getting older and did not like to sleep. He was sure he was getting old because everyone kept telling him that.

Obviously, when Ben asked me to become his physician, I agreed. Ben agreed to come to the medical school and

From Center for the Study of Aging and Human Development and the Department of Medicine, Duke University Medical Center, Durham 27710.

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talk to the class to which I was giving lectures on aging. This provided him with purpose and provided me with an excellent guest lecturer. He would develop his own lesson plan utilizing his background and experiences. He talked to the students with dignity of the indignity and with humility of the humiliation and indifference. They heard wisdom and caring from a man dedicated to putting all of the rest of his life to use by telling them, the physicians who might care for him and other elderly patients, about the problems of aging, of disease, and of medications, and about the general needs of older people.

So, once every six weeks for the next four years with appropriate breaks, students would get a chance to talk to someone who experienced and understood loneliness, isolation, the days of the industrial revolution, wars in Europe and America, the Depression, eating alone, the problem

with medications, the lack of support from families, financial problems, medicare and medicaid, being sick, and being old in America in the early 1980s. This wonderful and gentle man understood that each time he came from the nursing home with his doctor to help in teaching medical students about growing old in America he was still being of use.

Ben taught and helped me to focus, at a point early in my career, on the broad aspects of geriatric medicine that are not readily discernible in formal geriatric internal medical training. With that start, it was much easier to integrate specific clinical medical information about the elderly into the broad approach needed to be a practicing geriatrician. To paraphrase Ben's standard comment, "it will help to understand that old age is not wasted on the old, it's wasted by the young." ■

Bulletin Board

Continuing Medical Education

Please note: The Continuing Medical Education Programs at Bowman Gray, Duke, East Carolina (ECU) and UNC Schools of Medicine, Dorothea Dix, and Burroughs Wellcome Company are accredited by the American Medical Association. Therefore CME programs sponsored or cosponsored by these schools automatically qualify for AMA Category I credit toward the AMA's Physician Recognition Award, and for North Carolina Medical Society Category A credit. Where AAFP credit has been obtained, this also is indicated.

IN STATE

March 21

Eighth Annual Pulmonary Disease Update

Place: Greenville

Fee: \$55

Credit: 6.5 hours Category I AMA

Info: The Office of CME, ECU School of Medicine, Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

March 26-27

Growth Control and Cancer: Molecular Approaches and Clinical Implications

Place: Chapel Hill

Info: Dianne Shaw, Lineberger Cancer Research Center, School of Medicine, University of North Carolina, Chapel Hill 27514. 919/966-3036

April 3

Rehabilitation Medicine: Head Injuries

Place: Greenville

Credit: 7 hours Category I AMA

Info: The Office of CME, ECU School of Medicine, P.O. Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

April 3-5

Sixth Annual Ultrasound Symposium

Place: Greensboro

Credit: 16 hours Category I AMA

Info: Sharon Hughes, President, NC Ultrasound Society. 919/748-4505

April 9

North Carolina Clinical Neuro-Ophthalmology Review

Place: Chapel Hill

Info: Baird S. Grimson, M.D., Dept of Ophthalmology, University of North Carolina, 617 Clinical Science Bldg. 229H, Chapel Hill 27514. 919/966-5296

April 10

Plasma Cell Myeloma and Related Diseases

Place: Durham

Credit: 6 hours Category I AMA

Fee: \$75

Info: Myeloma Symposium, Box 3096 DUMC, Durham 27710

April 10-11

Advanced Cardiac Life Support Provider Course

Place: Asheville

Credit: 16 hours Category I AMA

Fee: \$200

Info: Daniel L. Dolan, M.D., MAHEC, 501 Biltmore Ave., Asheville 28801-4686. 704/258-0881

April 11-22

Highway Safety Conference

Place: Boone

Fee: \$25

Credit: 7 Hours Category I AMA

Info: W. Douglas Wooten, Head, Highway Safety Branch, Div. of Health Service, P.O. Box 2091, Raleigh 27602. 919/733-3222

April 22

Neonatal Emergencies: Recognition and Treatment

Place: Greenville

Credit: 6 hours Category I AMA

Fee: \$55

Info: Office of CME, ECU School of Medicine, P.O. Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

April 25

Fifteenth Annual New Bern Symposium: The Care of the Elderly

Place: New Bern

Info: Wm. B. Hunt, Jr., M.D., Symposium Director, P.O. Box 2157, New Bern 28560. 919/633-8608

May 8-9

Emergencies of the Lung and Gut in Pediatric Patients

Place: Durham

Fee: \$90

Credit: 10 hours Category I AMA

Info: Dr. Alexander Spock, M.D., Duke University Medical Center, Box 2994, Durham 27710. 919/681-3364

May 13

Common Diagnostic Problems in Surgical Pathology: A Practical Approach

Place: Greenville

Fee: \$55

Credit: 7 hours Category I AMA

Info: The Office of CME, ECU School of Medicine, P.O. Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

May 22

4th Annual Eye Conference — "Ocular Tumors"

Place: Winston-Salem

Info: Kirk Huske, Bowman Gray School of Medicine of Wake Forest University, Graylyn Conference Center, Winston-Salem 27103. 919/748-3971

June 15-17

Surgery for Coronary Artery Disease

Place: Durham

Fee: \$460 ACC members; \$525 others

Credit: 17 hours Category I ACCME

Info: Registration Secretary, Extramural Programs Dept., American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 800/253-4636; in MD or AK 301/897-5400

Nursing

Except where otherwise noted, contact Nettie Wilburn, CPS, Office of Continuing Education, University of North Carolina, Chapel Hill 27514. 919/966-3638

May 13-14

The Systematic Process of Instructional Development

Place: Chapel Hill

Credit: 13.2 CEUs pending

Fee: \$110

June 1-5

Preparation for NCLEX-RN

Place: Chapel Hill

Credit: 3.39 CEUs

Fee: \$75 UNC-CH students; \$85 others

June 1-19

Summer Institute: Gerontology for Nurse Educators
 Place: Chapel Hill
 Credit: 3 CEUs
 Fee: \$3

OUT OF STATE**March 14-15**

Contemporary Trends in Diagnostic Nuclear Medicine
 Place: San Francisco, CA
 Fee: \$352
 Info: 415/476-5808

March 16-20

Diagnostic Imaging 1987
 Place: Kauai, HI
 Credit: 24 hours Category I AMA
 Fee: \$495
 Info: 415/476-5808

March 19-20

Hospital Infections in 1987 and Beyond: New Issues, Problems and Strategies
 Place: Hilton Head Island, SC
 Credit: 9 hours Category I AMA, CEUs
 Info: Loraine E. Price, B.S.N., C.I.C., Div. of Infectious Diseases, UNC School of Medicine, 547 Clinical Sciences Bldg. 229H, Chapel Hill 27514. 919/966-3242

March 29-April 1

Cardiology Update
 Place: Phoenix, AZ
 Credit: 26 hours Category I AMA
 Fee: \$395 approx.
 Info: Lisa Krehbiel, Institute for Medical Studies, 30131 Town Center Dr. Ste 215, Laguna Niguel, CA 92677. 714/495-4499

April 2

School Health
 Place: Johnson City, TN
 Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

April 3-5

Ophthalmologic Plastic Surgery, Orbital Disease, and Neuro-Ophthalmology
 Place: Williamsburg, VA
 Fee: \$315
 Info: Kay Parrott, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 6-8

Newborn Screening for Sickle Cell Disease and Other Hemoglobinopathies
 Place: Bethesda, MD
 Credit: 13.5 hours Category I AMA
 Info: Nancy Cowan, Prospect Associates, 1801 Rockville Pike, Suite 500, Rockville, MD 20852. 301/468-6555

April 9-10

16th Annual School Health Education
 Place: Johnson City, TN
 Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

April 9-11

Thoracic Imaging Update
 Place: Monterey, CA
 Credit: 13 hours Category I AMA
 Fee: \$295
 Info: 415/476-5808

April 9-11

Current Concepts in Vascular Surgery
 Place: Philadelphia, PA
 Info: Fay Zelle, Hahnemann University, Broad and Vine Streets, M.X. 623, Philadelphia, PA 19102. 215/448-8263

April 10-12

OB.GYN and Abdominal Sonography: Update '87
 Place: San Francisco, CA
 Credit: 14.5 hours Category I AMA
 Fee: \$325
 Info: 415/476-5808

April 10-12

5th Annual MCV Symposium: New Trends in Anesthesia
 Place: Williamsburg, VA
 Fee: \$275
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 10-12

22nd Annual Pediatric Springfest
 Place: Williamsburg, VA
 Fee: \$250
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 12-18

Pathology Update 1987: Review of Current Concepts and New Developments
 Place: Baltimore, MD
 Info: American Society of Clinical Pathologists, 800/621-4142 (in IL 312/738-4890)

April 23-25

Cardiology
 Place: Johnson City, TN
 Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

April 23-25

23rd Annual Postgraduate Course in Radiology: The Chest
 Place: Richmond, VA
 Fee: \$325
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 24-25

The Terminally Ill Patient: Psychological, Social, Legal, and Ethical Issues
 Place: Boston, MA
 Info: Harvard Medical School, Dept. of CME, Boston, MA 02115. 617/732-1525

April 24-26

9th Annual Conference on Emergency Medicine for the Primary Care Physician
 Place: Williamsburg, VA
 Fee: \$295
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 24-26

7th Annual Clinical Concerns in Primary Care: Office Cardiology
 Place: Williamsburg, VA
 Fee: \$295
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 27-May 2 (and March 2-7)

22nd Annual Family Practice Symposium
 Place: Augusta, GA
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

April 30-May 2

Clinical Nuclear Cardiology: Case Review with the Experts
 Place: Bethesda, MD
 Credit: 21.5 hours Category I AMA
 Fee: \$415-465
 Info: American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 800/253-4636 (in MD, 301/897-5400, ext 241)

April 30-May 3

North American Society of Pacing and Electrophysiology
 Place: Boston, MA
 Credit: 16 hours Category I AMA (for General Sessions)
 Fee: \$90-215
 Info: NASPE Registration, 13 Eaton Court, Wellesley Hills, MA 02181. 617/237-1866

May 2-9

Doppler and 2-D Echocardiology
 Place: Newport Beach, CA
 Fee: \$895 approx.
 Credit: 40 hours Category I AMA
 Info: Lisa Krebbiel, Institute for Medical Studies, 30131 Town Center Dr., Ste. 215, Laguna Niguel, CA 92677. 714/495-4499

May 8-10

6th Annual MCV Cardiology Conference
 Place: Williamsburg, VA
 Fee: \$325
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

May 14-16

Vascular Surgery 1987: Third International Vascular Symposium
 Place: New York, NY
 Fee: \$400
 Credit: 24 hours Category I AMA
 Info: Ann J. Boehme, Assoc. Director for CME, Long Island Jewish Medical Center, New Hyde Park, NY 11042. 718/470-8650

May 18-19

14th Annual Hans Berger Day and EEG Symposium
 Place: Richmond, VA
 Fee: \$250
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

May 19-22

Cell Calcium Metabolism '87: Physiology, Biochemistry, Pharmacology, and Clinical Implications
 Place: Washington, D.C.
 Info: Dr. Gary Fiskum, Dept. of Biochemistry, The George Washington University of Medicine and Health Sciences, 2300 Eye St. NW, Washington, D.C. 20037.

May 23-25

Gynecologic Urology and Pelvic Surgery
 Place: Williamsburg, VA
 Fee: \$260
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

May 26-30

Fifth Annual Cardiology Update
 Place: Honolulu, HI
 Fee: \$395
 Info: Lisa Krebbiel, 30131 Town Center Dr., Ste. 215, Laguna Niguel, CA 92677. 714/495-4499

May 30

Tough Psychiatry Problems in Medical Practice
 Place: Gatlinburg, TN
 Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

June 1-5

Basic Mechanisms of Cardiovascular Diseases: Implications for Prevention and Therapy
 Place: London, England
 Credit: 26 hours Category I AMA
 Fee: \$425
 Info: London Cardiology Course, Div. of CME-Vanderbilt, CCC-5326 Medical Center North, Nashville, TN 37232. 615/322-4030

June 3-7

Eleventh Annual Postgraduate Course on Rehabilitation of the Brain-Injured Adult and Child
 Place: Williamsburg, VA
 Fee: \$285
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Station, Richmond, VA 23298-0001. 804/786-0494

June 4-6

11th Annual Update Cardiology for the Primary Physician
 Place: Charleston, SC
 Credit: 19 Hours Category I AMA
 Fee: \$335-400
 Info: Registration Secretary, Extramural Programs Dept., American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 800/253-4636 (in MD and AK, 301/897-5400, ext 226)

June 9-13

4th Annual Adult Infectious Disease Seminar — Current Update
 Place: Hilton Head Island, SC
 Credit: 19 hours Category I AMA, AAFP
 Fee: \$295
 Info: George M. Converse, M.D., Director, Medical Education, Lloyd Noland Hospital and Health Centers, 701 Ridgeway Rd., Fairfield, AL 35064. 800/845-6131 (in SC, 800/922-7042)

June 10-13

Post-Graduate Course: Dermatology for Non-Dermatologists
 Place: Myrtle Beach, SC
 Credit: 15 hours Category I AMA
 Fee: \$200-350
 Info: Div. of Dermatology, Box 3135, Duke University Medical Center, Durham 27710. 919/684-2504

June 11-13

Current Advances in Pediatric Practice
 Place: Gatlinburg, TN
 Credit: 12 hours Category I/PREP, AAP, AAFP
 Info: Dr. Sandra Loucks, University of Tennessee Memorial Research Center and Hospital, Dept. of Pediatrics, 1924 Alcoa Highway, Knoxville, TN 37920. 615/544-9331

June 15-17

Management of Clinically Localized Prostate Cancer
 Place: Bethesda, MD
 Credit: 14 hours Category I AMA
 Info: Nancy Cowan, Prospect Associates, 1801 Rockville Pike, Suite 500, Rockville, MD 20852. 301/468-6555

June 15-18

18th Annual Internal Medicine Symposium
 Place: Kiawah Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

July 9-11

Clinical Obstetrics
 Place: Kiawah Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

July 13-16

Clinical Cardiology
 Place: Kiawah Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

July 17-19

Practical Internal Medicine: Selected Topics for the Internist
 Place: Virginia Beach, VA
 Fee: \$295
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Station, Richmond, VA 23298-0001

July 22-26

Critical Care Medicine
 Place: Kiawah Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

July 27-29

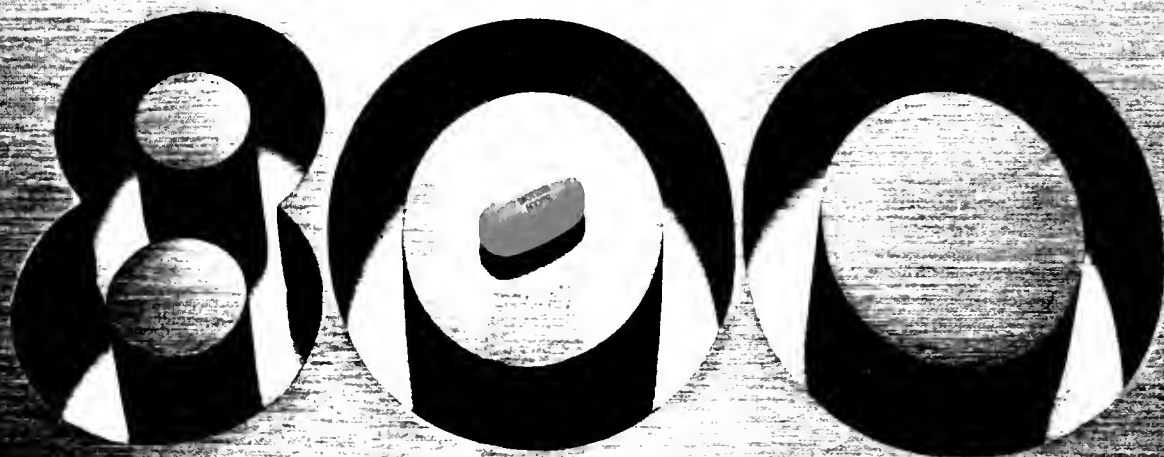
Pediatric Update 1987
 Place: Kiawah Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

July 31-August 2

The 9th Annual Pediatric Primary Care Conference: Pediatrics at the Beach
 Place: Virginia Beach, VA
 Fee: \$275
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Station, Richmond, VA 23298-0001

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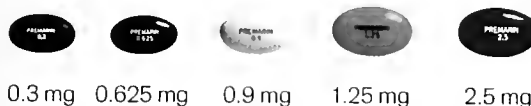
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BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION AND PATIENT INFORMATION, SEE PACKAGE CIRCULARS.)

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PREMARIN® Brand of conjugated estrogens Vaginal Cream in a nonfluorinating base

1 ESTROGENS HAVE BEEN REPORTED TO INCREASE THE RISK OF ENDOMETRIAL CARCINOMA

Three independent case control studies have reported an increased risk of endometrial cancer in postmenopausal women exposed to exogenous estrogens for more than one year. This risk was independent of the other known risk factors for endometrial cancer. These studies are further supported by the finding that incidence rates of endometrial cancer have increased sharply since 1969 in eight different areas of the United States with population-based cancer reporting systems, an increase which may be related to the rapidly expanding use of estrogens during the last decade. The three case control studies reported that the risk of endometrial cancer in estrogen users was about 4.5 to 13.9 times greater than in nonusers. The risk appears to depend on both duration of treatment and on estrogen dose. In view of these findings, when estrogens are used for the treatment of menopausal symptoms, the lowest dose that will control symptoms should be utilized and medication should be discontinued as soon as possible. When prolonged treatment is medically indicated, the patient should be reassessed on at least a semiannual basis to determine the need for continued therapy. Although the evidence must be considered preliminary, one study suggests that cyclic administration of low doses of estrogen may carry less risk than continuous administration, it therefore appears prudent to utilize such a regimen. Close clinical surveillance of all women taking estrogens is important. In all cases of undiagnosed persistent or recurring abnormal vaginal bleeding, adequate diagnostic measures should be undertaken to rule out malignancy. There is no evidence at present that "natural" estrogens are more or less hazardous than "synthetic" estrogens at equieffective doses.

2 ESTROGENS SHOULD NOT BE USED DURING PREGNANCY

The use of female sex hormones, both estrogens and progestogens, during early pregnancy may seriously damage the offspring. It has been shown that females exposed in utero to diethylstilbestrol, a non-steroidal estrogen, have an increased risk of developing in later life a form of vaginal or cervical cancer that is ordinarily extremely rare. This risk has been estimated as not greater than 4 per 1,000 exposures. Furthermore, a high percentage of such exposed women (from 30% to 90%) have been found to have vaginal adenosis, epithelial changes of the vagina and cervix. Although these changes are histologically benign, it is not known whether they are precursors of malignancy. Although similar data are not available with the use of other estrogens, it cannot be presumed they would not induce similar changes. Several reports suggest an association between intrauterine exposure to female sex hormones and congenital anomalies, including congenital heart defects and limb reduction defects. One case control study estimated a 4.7-fold increased risk of limb reduction defects in infants exposed in utero to sex hormones (oral contraceptives, hormone withdrawal tests for pregnancy, or attempted treatment for threatened abortion). Some of these exposures were very short and involved only a few days of treatment. The data suggest that the risk of limb reduction defects in exposed fetuses is somewhat less than 1 per 1,000. In the past, female sex hormones have been used during pregnancy in an attempt to treat threatened or habitual abortion. There is considerable evidence that estrogens are ineffective for these indications, and there is no evidence from well controlled studies that progestogens are effective for these uses. If PREMARN is used during pregnancy, or if the patient becomes pregnant while taking this drug, she should be apprised of the potential risks to the fetus, and the advisability of pregnancy continuation.

DESCRIPTION: PREMARN (conjugated estrogens, USP) contains a mixture of estrogens, obtained exclusively from natural sources, blended to represent the average composition of material derived from pregnant mares' urine. It contains estrone, equin, and 17 α -dihydroequin, together with smaller amounts of 17 α -estradiol, equin, and 17 α -dihydroequin as salts of their sulfate esters. Tablets are available in 0.3 mg, 0.625 mg, 0.9 mg, 1.25 mg, and 2.5 mg strengths of conjugated estrogens. Cream is available as 0.625 mg conjugated estrogens per gram.

INDICATIONS AND USAGE: PREMARN (conjugated estrogens tablets, USP). Moderate-to-severe vasomotor symptoms associated with the menopause. (There is no evidence that estrogens are effective for nervous symptoms or depression without associated vasomotor symptoms and they should not be used to treat such conditions.) Osteoporosis (abnormally low bone mass). Atrophic vaginitis. Kraurosis vulvae. Female castration.

PREMARIN (conjugated estrogens) Vaginal Cream is indicated in the treatment of atrophic vaginitis and kraurosis vulvae. PREMARN has not been shown to be effective for ANY PURPOSE DURING PREGNANCY AND ITS USE MAY CAUSE SEVERE HARM TO THE FETUS (SEE BOXED WARNING).

Concomitant Progestin Use: The lowest effective dose appropriate for the specific indication should be utilized. Studies of the addition of a progestin for 7 or more days of a cycle of estrogen administration have reported a lowered incidence of endometrial hyperplasia. Morphological and biochemical studies of the endometrium suggest that 10 to 13 days of progestin are needed to provide maximal maturation of the endometrium and to eliminate any hyperplastic changes. Whether this will provide protection from endometrial carcinoma has not been clearly established. There is a strong possibility of additional risks which may be associated with the inclusion of progestin in estrogen replacement regimens. (See PRECAUTIONS.) The choice of progestin and dosage may be important; product labeling should be reviewed to minimize possible adverse effects.

CONTRAINDICATIONS: Estrogens should not be used in women (or men) with any of the following conditions: 1. Known or suspected cancer of the breast except in appropriately selected patients being treated for metastatic disease. 2. Known or suspected estrogen-dependent neoplasia. 3. Known or suspected pregnancy (See Boxed Warning). 4. Undiagnosed abnormal genital bleeding. 5. Active thrombophlebitis or thromboembolic disorders. 6. A past history of thrombophlebitis, thrombosis, or thromboembolic disorders associated with previous estrogen use (except when used in treatment of breast or prostatic malignancy). 7. The choice of progestin and dosage may be important; product labeling should be reviewed to minimize possible adverse effects.

WARNINGS: Long-term continuous administration of natural and synthetic estrogens in certain animal species increases the frequency of carcinomas of the breast, cervix, vagina, and liver. There are now reports that estrogens increase the risk of carcinoma of the endometrium in humans. (See Boxed Warning.) At the present time there is no satisfactory evidence that estrogens given to postmenopausal women increase the risk of cancer of the breast, although a recent study has raised this possibility. There is a need for caution in prescribing estrogens for women with a strong family history of breast cancer or who have breast nodules, fibrocystic disease, or abnormal mammograms. A recent study has reported a 2- to 3-fold increase in the risk of surgically confirmed gallbladder disease in women receiving postmenopausal estrogens.

Adverse effects of oral contraceptives may be expected at the larger doses of estrogen used to treat prostatic or breast cancer or postpartum breast engorgement, it has been shown that there is an increased risk of thrombosis in men receiving estrogens for prostatic cancer and women for postpartum breast engorgement. Users of oral contraceptives have an increased risk of diseases, such as thrombophlebitis, pulmonary embolism, stroke, and myocardial infarction. Cases of fatal thrombosis, mesenteric thrombosis, and optic neuritis have been reported in oral contraceptive users. An increased risk of postpartum thromboembolic complications has also been reported in users of oral contraceptives. If feasible, estrogen should be discontinued at least 4 weeks before surgery of the type associated with an increased risk of thromboembolism, or during periods of prolonged immobilization. Estrogens should not be used in persons with active thrombophlebitis, thromboembolic disorders, or in persons with a history of such disorders in association with estrogen use. They should be used with

For atrophic vaginitis

PREMARIN® (Conjugated Estrogens)

Vaginal
Cream

0.625mg/g



caution in patients with cerebral vascular or coronary artery disease. Large doses (5 mg conjugated estrogens per day), comparable to those used to treat cancer of the prostate and breast, have been shown to increase the risk of nonfatal myocardial infarction, pulmonary embolism and thrombophlebitis. When doses of this size are used, any of the thromboembolic and thrombotic adverse effects should be considered a clear risk.

Benign hepatic adenomas should be considered in estrogen users having abdominal pain and tenderness, abdominal mass, or hypovolemic shock. Hepatocellular carcinoma has been reported in women taking estrogen-containing oral contraceptives. Increased blood pressure may occur with use of estrogens in the menopause and blood pressure should be monitored with estrogen use. A worsening of glucose tolerance has been observed in patients on estrogen-containing oral contraceptives. For this reason, diabetic patients should be carefully observed. Estrogens may lead to severe hypercalcemia in patients with breast cancer and bone metastases.

PRECAUTIONS: Physical examination and a complete medical and family history should be taken prior to the initiation of any estrogen therapy with special reference to blood pressure, breasts, abdomen, and pelvic organs, and should include a Papanicolaou smear. As a general rule, estrogen should not be prescribed for longer than one year without another physical examination being performed. Conditions influenced by fluid retention such as asthma, epilepsy, migraine, and cardiac or renal dysfunction, require careful observation. Certain patients may develop manifestations of excessive estrogenic stimulation, such as abnormal or excessive uterine bleeding, mastodynia, etc. Prolonged administration of unopposed estrogen therapy has been reported to increase the risk of endometrial hyperplasia in some patients. Oral contraceptives appear to be associated with an increased incidence of mental depression. Patients with a history of depression should be carefully observed. Preexisting uterine leiomyomata may increase in size during estrogen use. The pathologist should be advised of estrogen therapy when relevant specimens are submitted. If jaundice develops in any patient receiving estrogen, the medication should be discontinued while the cause is investigated. Estrogens should be used with care in patients with impaired liver function, renal insufficiency, metabolic bone diseases associated with hypercalcemia, or in young patients in whom bone growth is not complete. If concomitant progestin therapy is used, potential risks may include adverse effects on carbohydrate and lipid metabolism.

The following changes may be expected with larger doses of estrogen:

- Increased sulfobromophthalen retention
- Increased prothrombin and factors VII, VIII, IX, and X, decreased antithrombin III, increased norepinephrine-induced platelet aggregability
- Increased thyroxine binding globulin (TBG) leading to increased circulating total thyroid hormone, as measured by PBI, T4 by column, or T4 by radioimmunoassay. Free T3 resin uptake is decreased, reflecting the elevated TBG. Free T4 concentration is unaltered.
- Impaired glucose tolerance
- Decreased pregnandiol excretion
- Reduced response to metoprolol test
- Reduced serum folate concentration
- Increased serum triglyceride and phospholipid concentration.

As a general principle, the administration of any drug to nursing mothers should be done only when clearly necessary since many drugs are excreted in human milk.

ADVERSE REACTIONS: The following have been reported with estrogenic therapy, including oral contraceptives: breakthrough bleeding, spotting, change in menstrual flow, dysmenorrhea, premenstrual-like syndrome; amenorrhea during and after treatment, increase in size of uterine leiomyomata, vaginal candidiasis, change in cervical erosion and in depth of os, change in degree of cystitis-like syndrome, tenderness, enlargement, secretion (of breasts), nausea, vomiting, abdominal cramps, bloating, cholestatic jaundice, chloasma or melasma which may persist when drug is discontinued, erythema multiforme, erythema nodosum, hemorrhagic eruption, loss of scalp hair, hirsutism, steepening of corneal curvature, intolerance to contact lenses, headache, migraine, dizziness, mental depression, chorea; increase or decrease in weight, reduced carbohydrate tolerance, aggravation of porphyria, edema, changes in libido.

ACUTE OVERDOSEAGE: May cause nausea, and withdrawal bleeding may occur in females.

DOSEAGE AND ADMINISTRATION:

PREMARIN® Brand of conjugated estrogens tablets, USP

1. Given cyclically for short-term use only. For treatment of moderate to severe vasomotor symptoms, atrophic vaginitis, or kraurosis vulvae associated with the menopause (0.3 to 1.25 mg or more daily). The lowest dose that will control symptoms should be chosen and medication should be discontinued as promptly as possible. Administration should be cyclic (eg, three weeks on and one week off). Attempts to discontinue or taper medication should be made at three- to six-month intervals.

2. Given cyclically for long-term use only. For maintenance of bone mass: Female castration—1.25 mg daily cyclically. Adjust upward or downward according to response of the patient. For maintenance, adjust dosage to lowest level that will provide effective control. Osteoporosis—0.625 mg daily. Administration should be cyclic (eg, three weeks on and one week off).

Patients with an intact uterus should be monitored for signs of endometrial cancer and appropriate measures taken to rule out malignancy in the event of persistent or recurring abnormal vaginal bleeding.

PREMARIN® Brand of conjugated estrogens Vaginal Cream

1. Given cyclically for short-term use only. For treatment of atrophic vaginitis or kraurosis vulvae. The lowest dose that will control symptoms should be chosen and medication should be discontinued as promptly as possible.

Administration should be cyclic (eg, three weeks on and one week off).

Attempts to discontinue or taper medication should be made at three- to six-month intervals.

Treated patients with a intact uterus should be monitored closely for signs of endometrial cancer and appropriate diagnostic measures should be taken to rule out malignancy in the event of persistent or recurring abnormal vaginal bleeding.

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- Whitehead MI, Townsend PT, Pryse-Davies J, et al. Effects of estrogens and progestins on the biochemistry and morphology of the postmenopausal endometrium. *N Engl J Med* 1981;305:1589-1605. 2. Paterson MEL, Wade-Evans T, Sturdee DW, et al. Endometrial disease after treatment with oestrogens and progestogens in the climacteric. *Br Med J* 1980;280:822-824. 3. Magos AL, Brincat M, Studd JWW, et al. Amenorrhea and endometrial atrophy with continuous oral estrogen and progestogen therapy in postmenopausal women. *Obstet Gynecol* 1985;67:496-499. 4. Whitehead MI, Lane G, Siddle N, et al. Avoidance of endometrial hyperstimulation in estrogen-treated postmenopausal women. *Semin Reprod Endocrinol* 1983;1:141-152. 5. Barnes RB, Roy S, Lobo AA. Compaction of lipid and androgen levels after conjugated estrogen or depo-medroxyprogesterone acetate treatment in postmenopausal women. *Obstet Gynecol* 1985;66:216-219.

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Letters to the Editor

From the State Surgeon, North Carolina Army National Guard

To North Carolina Physicians:

For thirty years I have enjoyed a combined medical practice of civilian and military by belonging to the North Carolina National Guard. During this period I have observed our civilian physician numbers increase to the point of oversupply while physicians practicing military medicine in the militia of our state have been steadily decreasing in numbers.

This creates a shortage of physicians serving our own North Carolina guardsmen, some thirteen thousand of them, places our guardsmen at increased risk when they are in training status, deprives our physicians of the opportunities and experiences associated with field medicine, deprives our physicians of the varied experiences associated with travel to distant states and to foreign countries in training status, and deprives our physicians of the satisfaction of supporting our nation, state, and more especially our guardsmen neighbors as they serve their country, and finally, denies themselves a very substantial addition to their own retirement income. In some needed specialties, the guard can help by repaying up to \$20,000 in medical school education loans.

I am and have been a guardsman by choice. I was not at risk of the draft or any other pressures when I applied and accepted a commission in the Medical Corps in the North Carolina National Guard. There are many ways to serve one's nation. I chose this way. If any North Carolina physicians are interested in serving their fellowman and their country and at the same time being richly rewarded tangibly and intangibly, I urge them to contact Captain Regan or Sergeant First Class Denison at 919/733-3770, Ext 213 or 1-800/662-1872, and discuss their situation and their opportunities.

"Every professional owes something of himself to his country."

Corbett L. Quinn, M.D., State Surgeon
North Carolina Army National Guard
P.O. Box 189
Magnolia, NC 28453-0189

To the Editor:

The Pediatric Branch of the National Cancer Institute is seeking the referral of pediatric patients with cancer for the evaluation of several new treatment programs.

A variety of innovative treatment protocols has been developed for patients with either newly diagnosed or previously treated childhood malignancies.

We are interested in seeing newly diagnosed patients with

acute leukemia, Hodgkins and non-Hodgkins lymphoma, rhabdomyosarcoma, osteogenic sarcoma and Ewing's sarcoma (or other bony or soft tissue sarcomas). Previously treated patients with these and other diagnoses (including primary and metastatic CNS malignancies) may be eligible for treatment.

Clinical protocols emphasize new and experimental treatment approaches including high dose chemotherapy, autologous bone marrow rescue, and Phase I and Phase II studies of new chemotherapeutic agents and biological response modifiers, including interleukin. Selected patients with refractory malignancies (e.g., leukemia) who do not have an appropriate HLA match may be eligible for a new bone marrow transplantation program evaluating the feasibility of transplanting bone marrow from an unrelated, MHC un-matched donor which has been treated to eliminate T cell contamination.

Our program stresses close communication and cooperation with referring physicians. Every effort is made to keep you fully informed as to the status of your patients and in most situations patients will promptly return to your care for joint follow-up in collaboration with the National Cancer Institute. In this way, the limited number of children with cancer can be enrolled in the clinical research process while being cared for in their home community.

Patients must be willing to travel to the Clinical Center initially and at periodic intervals. There is no charge to the patient for medical, surgical or other hospital services rendered as the necessary part of their participation in our clinical research protocols.

To refer a patient or to obtain further information, please call or write:

Philip A. Pizzo, M.D.
Chief, Pediatric Branch
National Cancer Institute
Building 10 — Room 13N240
Bethesda, MD 20892
301/496-4256 (Collect)

A Follow-up on a Case Report

To the Editor:

In the September 1986 issue of the NCMJ we described a 36-year-old woman with acute nonlymphocytic leukemia (ANLL) who had strong clinical and pathologic evidence that she had been "cured" of hepatic candidiasis (Powell BL, Jackson DV Jr, Craig JB, Richter JE, Capizzi RL, Cure of Hepatic Candidiasis in Acute Leukemia, 1986;47:393-5). In brief, following successful induction therapy, this patient had hepatic (and probable splenic) candidiasis doc-

umented by CT Scan and laparoscopy with directed liver biopsies. She was treated with a prolonged course of amphotericin B and 5-fluorocytosine. Clinical response to therapy was confirmed by gradual improvement in the radiographic abnormalities, negative laparoscopy with directed liver biopsies on two separate occasions, and two successful reinductions for relapsed ANLL without evidence of recurrent hepatosplenic candidiasis despite prolonged periods of granulocytopenia. At the time the manuscript was submitted, the patient had just completed a fourth induction attempt and remained free of evidence of hepatic disease over 30 months after diagnosis of hepatic candidiasis. Despite achieving transient fourth and fifth responses to induction chemotherapy, the patient subsequently died from an intracerebral hemorrhage during her seventh induction attempt (39 months after diagnosis of hepatic candidiasis). Permission for autopsy was granted; findings included multiple well-demarcated partially calcified nodules in the liver, spleen and kidneys. Microscopically, these nodules consisted of areas of coagulation necrosis encapsulated by fibrous connective tissue; Gomori methenamine silver stain showed small numbers of budding yeasts with pseudohyphae within the areas of necrosis. Cultures of the areas grew *Candida albicans*.

It is impossible to determine whether these calcified granulomatous foci represent old deposits of *Candida albicans* successfully walled off by host defenses and were of no clinical significance, chronic smoldering infection, or reinfection since the original diagnosis and treatment of hepatic \pm splenic candidiasis over three years earlier. In any case, these findings further emphasize the difficulty of eradicating visceral *Candida* infections in a patient with acute leukemia.

Bayard L. Powell, M.D.

Don V. Jackson, Jr., M.D.

Paula E. Szytko, M.D.

Department of Medicine

Bowman Gray School of Medicine

Wake Forest University

300 South Hawthorne Road

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To the Editor:

Your recent article in the *North Carolina Medical Journal* (Happy, Communicative and Understanding Doctors — The Roles of "Humanities" and Bioscience, 1986;47:561-2) has occupied my thoughts a great deal during my Christmas vacation and I feel compelled to respond to several of your points before I begin my next rotation at Duke University Medical School. Whereas I essentially agree with your observation that course content and the behavior of doctors are poorly correlated and find your four goals of a general education to be adequate, I believe out of my own experience as a religion and English major at UNC-Chapel Hill that study of the humanities has some very specific contributions to offer the would-be physician.

In our science-influenced modern compulsion to classify and speciate all things, education at the university level has

been divided into various departments and disciplines such that the different systems of learning and knowing are often separated from one another. This separation filters down to the structure of the university teaching system itself. The scientific method, with its heavy emphasis on factual information gathered from observation and quantitation becomes enshrined in the natural and social science departments. Other methods of knowing and learning, such as critical analysis and argument, are often the domain of the humanities departments at the undergraduate level. The student who focuses his or her energies very exclusively in the sciences will likely spend his or her four years at college learning an enormous body of facts that have been accumulated as a direct result of the application of the scientific method. He or she will learn in the lab the skills necessary to quantify repeatable observations. His or her examinations will consist mostly of true-false, multiple choice, and short answer questions with specific answers that are either right or wrong. Upon graduation this student should have an excellent grasp of bioscience and its implications for what it is to be human and what we can achieve as humans using the enormous tools of the scientific method.

The student of the humanities is likely to have a very different kind of education. He or she will spend a great deal of time reading and analyzing other people's subjective opinions on a wide variety of subjects such as literature, history, art, and philosophy. Much less energy is likely to be spent on learning objective facts and more is spent critically analyzing various arguments and learning to understand what a specific perspective or approach can teach. This student is likely to be evaluated by his or her ability to write various papers and essays conveying his or her own analysis of what has been read and discussed in class. Or this student may be evaluated by his or her ability to effectively communicate in a foreign language or in one of the fine arts. When he or she graduates, this student should understand that any system of knowledge has its own set of questions with its own built-in answers which are best evaluated by comprehending the system as a whole and asking what such a system can offer to enrich our understanding of what it is to be human.

It is clear that both skills taught in the humanities departments of universities and those taught in the science departments have very important contributions to offer to those students interested in being physicians as well as any person seeking an integrated quality education. What has been a concern to some observers in recent years is the heavy emphasis many pre-medical students place upon the natural sciences to the exclusion of other courses. This is a legitimate concern, for a physician who has not acquired the basic skills of analysis and critical thinking cannot effectively approach the diagnosis and treatment of the patients he or she desires to serve. In simple terms these analytic skills are often taught in the undergraduate curricula of our universities most effectively in the humanities departments. To prove my hypothesis go to any university on

any day and objectively measure the amount of discussion in a literature or history class and compare it with that in the local physical chemistry class discussing, say, the laws of thermodynamics. If discussion-level correlates with the amount of active thinking occurring, as I believe it does, then more often than not my point will be proven. The lecture-style format used so extensively in the undergraduate teaching of the sciences seldom encourages any more vigorous mental exercise in the classroom than passive listening and frantic note-taking.

A second point with which I disagree strongly is the assumption that an understanding of the biological basis for behavior will somehow allow a doctor to more effectively communicate with his patients or to become more tolerant of their behavior. Recent history teaches us that the increase in technical knowledge does not correspond with an increased capacity for tolerance on the part of the human race. An understanding of bioscience is only one part of the overall contribution that the many methods of knowing and learning can contribute to the possibility of more tolerance and better communication. The relationship between a doctor and his or her patient may perhaps be improved by the awareness on the part of the doctor of "the wide differences in brain anatomy and the effects of those differences on the behavior of the patient," but so too may the relationship perhaps be improved by an understanding on the part of the doctor of the patient's religious, cultural, or social history and what these factors may reveal about the patient's values as they pertain to his or her own health.

With expertise in the biosciences without any understanding of the humanities a physician is merely a highly-paid technician. Likewise an understanding of the humanities without knowledge of the observations and principles upon which medical science is built is inadequate for the important role of the physician in our society. At a time when the role of the physician in changing daily, when health care costs are gobbling up larger and larger amounts of our gross national product, when medical science is growing exponentially and creating ethical and economic quagmires with each new discovery, the physician's duty as "good citizen" necessitates broader educational skills than just those being taught in our undergraduate science departments today. Any students who believe pre-medical education stops at the chemistry lab doors may find themselves inadequately prepared for the impending changes in the health professions and their ability to help shape them.

Grace Emerson Terrell
Medical Student
DUMC class of '89

To Grace Emerson Terrell:

I enjoyed reading your thoughtful and well phrased letter. I agree that the non-biologist can learn by experience the many and varied reactions between people. Unfortunately the non-biologist can only be descriptive. Not knowing the biologic basis of behavior, the explanations for differences

will remain unclear and mystical. Differences in brains are the basis for differences in behavior. Science is slowly defining these structural differences. Instruction in this area is more likely to facilitate the development of doctors who are interested in people, tolerant of their differences and able to communicate with persons of varied backgrounds than any number of courses in the humanities.

I hope that we will continue this discussion over the years that you are at Duke.

Eugene A. Stead, Jr., M.D.
Editor, North Carolina Medical Journal

Responses to Dr. Crist's article and the letters to the editor that it prompted

Editor's note: For our physicians in the Western part of the state who may have missed the following article, we reprint it with permission from the Associated Press.

GREENSBORO (AP)—A *North Carolina Medical Journal* editorial (Sobering Thoughts, 1986;47:511) urging doctors to counter opposition toward sex education, birth control and abortion has drawn angry replies.

The editorial, written by Dr. Takey Crist of the Crist Clinic for Women in Jacksonville, said the foundation laid down by such groups as Planned Parenthood was "being crippled by our government, the fundamentalists, the Catholic hierarchy and our litigious society." It said those "forces, working together, are destroying our patients' rights to reproductive freedom."

Crist, an obstetrician and former professor of obstetrics and gynecology at the University of North Carolina at Chapel Hill, told the Greensboro News & Record that he had written the editorial to show doctors that many health care issues affecting women and infants had been tangled up by the "politicizing and emotionalization" of sex education, birth control and abortion.

But critics contend that although the editorial is signed by Crist and his colleagues at the Crist Clinic, it appears also to be the view of the journal and, thus, the position of the state's 7,263-member Medical Society.

"About all it accomplished was to enable some more venom to be spit out," said Dr. Stephen J. Naso, a Charlotte surgeon who wrote a critical letter to the journal. He said "bigotry is at the basis of this, not religion."

Among the seven published letters (NCMJ 1987;48:45-7) severely criticizing the editorial was one from the Rev. John F. Donoghue, Catholic bishop of the Charlotte Diocese.

"The Church never has attempted to dictate to members what political stands they should take," Donoghue wrote.

Dr. Robert W. Prichard, chief of pathology at the Bowman Gray School of Medicine in Winston-Salem,

defended the right of the journal and the physicians to publish the article. He wrote in a letter that "the pope and other Roman Catholics are not shy about stating their opinions."

In an interview, Prichard, a member of the journal editorial board, said the reaction was predictable.

"There are a lot of angry people out there," he said. "Look at all the money Jesse Helms gets. I think it comes from angry, outraged people." Helms, a Republican, is a U.S. senator from North Carolina.

Crist said he was surprised by the furor the more recent editorial has created.

"You do abortions and you get death threats," he said. "Abortion clinics get bombed. These people call you murderers. If you try to encourage school boards to have responsible sex education, they accuse you of promoting pornography and being a sex maniac. Most doctors' practices can't take that, but I think it's time to act together."

The journal's editor, Dr. Eugene Stead, Duke University emeritus professor of medicine, said no apology or retraction was warranted or would be forthcoming.

Stead said his view of the controversy was that "certainly the Catholic Church does seem to complicate these (reproduction) problems for doctors caring for people."

The editorial, Stead said, does not represent the views of the medical journal or its sponsoring society. Not to have published the piece would have been censorship, Stead said.

To the Editor:

In a curiously deceptive if not naïve disavowal of editorial responsibility for what amounts to a singular denunciation of the Catholic Church and certain Protestant groups, the *North Carolina Medical Journal* justifies its November 1986 editorial by Crist et al on the basis of the Journal's policy of freedom of expression by its contributors.

It is difficult to believe that a contribution dealing with a sensitive social issue would be highlighted as an editorial rather than a letter if there were not at least sympathy with the viewpoint expressed. By editorializing an incendiary statement which seeks substantiation (both in the original and authors' response) by reference to extremist critics of the Church, the Journal seriously undermines its editorial credibility.

Stephen D. Mumford was dismissed in 1983 as a research scientist for Family Health International in North Carolina because of unwanted notoriety related to extreme criticisms of the Catholic Church. The Catholic League for Religious and Civil Rights, patterned after the Jewish Anti-Defamation League, characterizes Mumford's statements as exhibiting a "breath-takingly paranoid hatred of the Catholic Church."¹

Daniel Maguire, referred to in the authors' response, is

an ex-priest and at most a peripheral Catholic theologian. He is best known for his advocacy of outright active euthanasia² and can hardly be invoked as a reasoned moderate with respect to his views of the Church.

The sponsoring of an editorial places a distinct responsibility on the editorial staff of a journal to ensure a modicum of balance and fairness which was lacking in this instance.

Robert K. Nixon, M.D.
Clinical Professor of Medicine
Univ. of North Carolina
School of Medicine

References

- 1 Schwartz M. The persistent prejudice: anti-Catholicism in America. Our Sunday Visitor, Inc., 1984.
- 2 Kohl M., ed. Beneficent euthanasia. Prometheus Books, 1975.

Two responses concerning Bishop Donoghue's letter

To the Editor:

The Catholic Church's Bishop Donoghue says, "the Church never has attempted to dictate to members what political stands they should take" (NCMJ 1987;48:46).

The abortion issue is a political stand, as witnessed by the Supreme Court rulings on abortion, the opposition to abortion by conservative Republicans and the support of abortion by liberal Democrats.

There has never been a more politically oriented religious group than the Catholic Church.

I would hazard a guess that most of the doctors who oppose your editorial on sex education, birth control and abortion are Catholics.

George A. Yelverton, Jr.
3910 Manila Road
Greensboro 27406

To the Editor:

I am writing in answer to the letter to you from Bishop John F. Donoghue of Charlotte, which states, "the Church has never attempted to dictate to its members what political stands they should take." This is untrue.

Increasingly in the last decade, many Catholic dioceses and parishes in their official church papers have printed lists of political candidates to support or vote against. Such dictates are in violation of Sec. 501-c-3 of the U.S. Tax Code. ARM's (Abortion Rights Mobilization) federal court case charging the bishops with violations and the IRS for not enforcing the law has been in court for six years. In June, 1986, the U.S. District Court in New York held the Catholic bishops in "contempt of court" for not turning over documents, and fined them \$100,000 a day, stayed on appeal to the U.S. Circuit.

A few examples of these violations: 1) *Today's Catholic* of the San Antonio (Tex.) archdiocese on May 2, 1980, printed a list of candidates to support or oppose; 2) *The St. Cloud (Minn.) Visitor* on Aug. 17, 1978 and on other dates published similar lists of candidates; 3) St. Mary of Mercy Church, Our Lady of Loreto Church and others in the Pittsburgh area attacked Congressional candidates in the 1978

elections; 4) Cardinal Medeiros of Boston and Msgr. Leo Battista of Worcester, Mass. attacked Congressional candidates in the Sept., 1980, primaries. These are just a few of scores of examples — mainly attacking candidates for their abortion rights stands — that are being used as evidence in ARM's lawsuit.

Lawrence Lader, President
Abortion Rights Mobilization
175 Fifth Avenue, Suite 814
New York, NY 10010

Dr. Styron's reply to Dr. Stella:

Thank you very much for your letter which I have just received (published in NCMJ 1987;48:99). I appreciate your thoughts on these matters.

Rather than repeat my own ideas, which have been recorded (NCMJ 1987;48:47), I wish you would read the Letters to the Editor in the January issue of the *North Carolina Medical Journal*.

In the meantime I have asked each member of the Editorial Board to write a letter to the editor with his or her impressions on the article and on the Letters to the Editor.

Charles W. Styron, M.D.
Chairman, NCMJ Editorial Board
615 St. Mary's Street
Raleigh 27605

To the Editor:

The question concerning Dr. Crist's "editorial" in the November issue is not so much the opinions expressed or the accuracy thereof but whether opinions expressed in editorials actually reflect editorial policy. Despite disclaimers in the Bylaws of the North Carolina Medical Society, I suspect that most readers of the Journal consider editorials as reflecting the opinions and policies of the publication. Accordingly, it would seem appropriate to publish "editorials" on controversial subjects in the letter section unless

the views expressed are in fact the official position of the publication.

Jack Hughes, M.D.
Member, NCMJ Editorial Board
The Coppridge Urologic Group, P.A.
923 Broad Street
Durham 27705

To the Editor:

I write to let you know — and anyone else who may wish to — that I — as a member of the Editorial Board — wholeheartedly endorse your stance (see Response from the Editor, NCMJ 1987;48:47) in the matter of the signed editorial by Doctor Crist et al.

William B. Blythe, M.D.
Member, NCMJ Editorial Board
The University of North Carolina
School of Medicine
Old Clinic Building 226 H
Chapel Hill 27514

In appreciation of "Hole in the Head" Article

To Dr. Linzer:

I enjoyed reading your paper from the *North Carolina Medical Journal*, in January 1987, "Eosinophilic Granuloma" (Darrow D. and Linzer M.; 48:15). I have been interested in this since I wrote the third paper of my career and published it in the very first issue of the *Journal of Neurosurgery* in 1944. The patient I operated on was a man who had come under my care at one of the Army hospitals in 1943 and subsequently was transferred to Pete Campbell who did a cranioplasty on him. Your coverage of this problem was very good.

Eban Alexander, Jr., M.D.
Bowman Gray School of Medicine
Department of Surgery
300 South Hawthorne Road
Winston-Salem 27103

Study Announcement

A study testing the effectiveness of ranitidine in the treatment of esophagitis is being conducted by the Division of Digestive Diseases at the University of North Carolina at Chapel Hill. We are actively recruiting patients with symptomatic reflux esophagitis to be involved in this six-month study. Evaluation and treatment during the study will be

done at no cost to the patient. In addition, patients will be reimbursed for travel expenses. If you have a patient who may be interested or have any questions about the study, please contact the Division of Digestive Diseases at 919/966-2511. We appreciate your assistance in informing others of this study.



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Index to Advertisers

Allscrips Pharmaceuticals, Inc.	110	Lewis Medical Instruments Inc.	147
Ayerst Laboratories	116a-d; 164b-d	Medical Mutual Insurance Company of N.C.	170
B & B X-Ray, Inc.	120	Medical Protective Company	123
Blue Cross and Blue Shield of North Carolina	126	MICA Information Systems	172
Burroughs Wellcome Co.	136	National Staffing Services Corp.	109
Campbell Laboratories, Inc.	156	NCNB	131
Carolina Manor	125	Roche Laboratories	121, 122; 145; Cover 3, 4
Charter Northridge Hospital	116	Roerig	132b-d
Crompton Company	Cover 2	The Upjohn Company	164a
Eli Lilly & Company	132a	U.S. Air Force	132
Glaxo, Inc.	156a-d	U.S. Army	144
Hinrichs Financial Group	124	U.S. Army Reserve	115, 144
Humana Medfirst	125	Winchester Surgical Supply Co.	161
Knoll Pharmaceuticals	124a-b; 125	Wrightsville Properties	112

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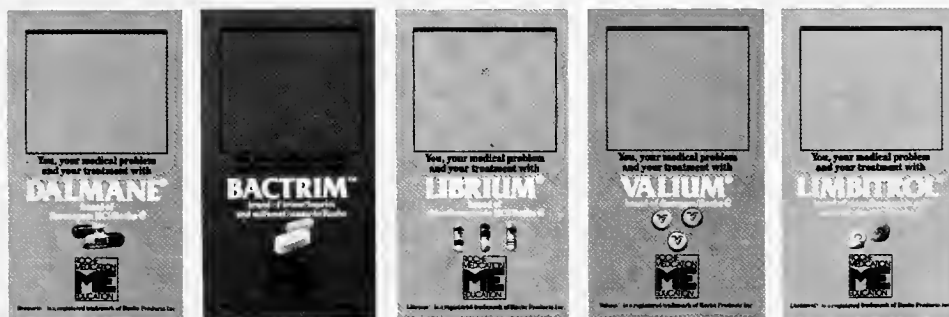
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Number 4

North Carolina Medical Journal

For Doctors and their Patients

Fire Fighters in North Carolina: In-Line-of-Duty Deaths

Lucy Fort, R.N.
Patricia D. Griggs, R.N.

Two Views of a Patient with Progressive Dementia

Albert Heyman, M.D.
Lisa Gwyther, M.S.W.

When Your Patient Decides To Die

Robert J. Sullivan, Jr., M.D.

133rd Annual Session
April 29 - May 2

Contents Page 175



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North Carolina Medical Journal

FOR DOCTORS AND THEIR PATIENTS

Contents / April 1987, Volume 48, Number 4

On the cover: photo by Chuck Liddy, © Durham Herald Co., Inc.

- 179 133rd Annual Session, North Carolina Medical Society: Schedule

SPECIAL ARTICLES

- 181 Two Views of a Patient with Progressive Dementia *Albert Heyman and Lisa Gwyther*
182 Scientific View: Subcortical Arteriosclerotic Encephalopathy (Binswanger's Disease):
Report of a Case Simulating Psychiatric Disease and Normal Pressure Hydrocephalus
Barrie J. Hurwitz, Albert Heyman, Peter C. Burger, and Burton P. Drayer
187 A Family's View of Progressive Dementia *Myrna Doernberg*

LEARNING WITHOUT WORDS

- 196 An Unusual Presentation of Pseudomembranous Colitis *Russell D. Yang and Virginia Byers Kraus*

FOR PATIENTS

- 203 Fire Fighters in North Carolina: In-Line-of-Duty Deaths *Lucy Fort and Patricia D. Griggs*
207 Drug Solution Among High School Students *Richard D. Adelman*

SCIENTIFIC ARTICLE

- 211 Radiology and Surgery in the Treatment of the Complications of Acute Pancreatitis
Herbert J. Proctor, John A. Schwartz, Robert Rutledge, and Matthew A. Mauro

SOCIOECONOMICS

- 218 Clinical Decision Making in a Cost Conscious Era: Cost Effective Evaluation of
Clinical Decision Making *Andrew G. Wallace*

LEARNING FROM A PATIENT

- 223 When Your Patient Decides To Die *Robert J. Sullivan, Jr.*

BULLETIN BOARD

- | | | | |
|-----|------------------------------------|-----|---------------------------|
| 225 | Letters to the Editor | 234 | In Memoriam |
| 228 | New Members | 238 | Classified Advertisements |
| 229 | Continuing Medical Education | 239 | Instructions to Authors |
| 233 | Official Call — House of Delegates | 240 | Index to Advertisers |

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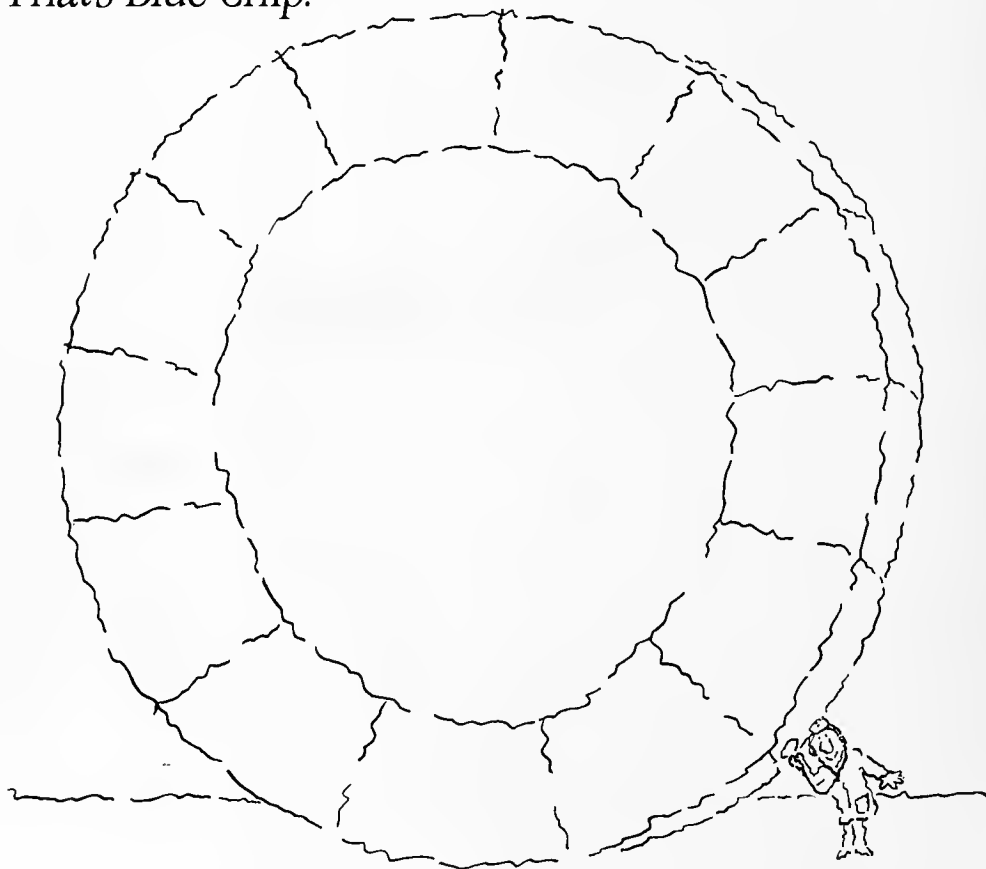
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MICROBIOLOGY: The bactericidal activity of ceftriaxone results from inhibition of cell wall synthesis. Ceftriaxone has a high degree of stability in the presence of beta-lactamases, both penicillinases and cephalosporinases of gram-negative and gram-positive bacteria. Ceftriaxone is usually active against the following microorganisms *in vitro* and in clinical infections (see Indications and Usage):

GRAM-NEGATIVE AEROBES: *Enterobacter aerogenes*, *Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae* (including ampicillin-resistant strains), *H. parainfluenzae*, *Klebsiella* species (including *K. pneumoniae*), *Neisseria gonorrhoeae* (including penicillinase and nonpenicillinase-producing strains), *Neisseria meningitidis*, *Proteus mirabilis*, *Proteus vulgaris*, *Morganella morganii* and *Serratia marcescens*.

Note: Many strains of the above organisms that are multiply resistant to other antibiotics, e.g., penicillins, cephalosporins and aminoglycosides are susceptible to ceftriaxone sodium.

Ceftriaxone is also active against many strains of *Pseudomonas aeruginosa*.

GRAM-POSITIVE AEROBES: *Staphylococcus aureus* (including penicillinase-producing strains) and *Staphylococcus epidermidis* (Note: methicillin-resistant *Staphylococcus* are resistant to cephalosporins including ceftriaxone). *Streptococcus pyogenes* (Group A beta-hemolytic *Streptococcus*), *Streptococcus agalactiae* (Group B *Streptococcus*) and *Streptococcus pneumoniae* (Note: Most strains of enterococci *Streptococcus faecalis* and Group D *Streptococcus* are resistant).

Ceftriaxone also demonstrates *in vitro* activity against the following microorganisms, although the clinical significance is unknown.

GRAM-NEGATIVE AEROBES: *Citrobacter freundii*, *Citrobacter diversus*, *Providencia species* (including *Providencia rettgeri*), *Salmonella species* (including *S. typhi*), *Shigella species* and *Acinetobacter calcoaceticus*.

ANAEROBES: *Bacteroides species*, *Clostridium species* (Note: most strains of *C. difficile* are resistant).

SUSCEPTIBILITY TESTING: Standard susceptibility disk method. Quantitative methods that require measurement of zone diameters give the most precise estimate of antibiotic susceptibility. One such procedure (Bauer-Warwick, M.M. Sherris, J.C. Tench, M. Antibiotic Susceptibility Testing by a Standardized Single Disk Method, Am J Clin Pathol 45:493-496, 1966; Standardized Disk Susceptibility Test, Federal Register 39:19182-19184, 1974; National Committee for Clinical Laboratory Standards, Approved Standard M7-A2, Performance Standards for Antimicrobial Disk Susceptibility Tests, July 1975) has been recommended for use with disks to test susceptibility to ceftriaxone.

Laboratory results of the standardized single disk susceptibility test using a 30 mcg ceftriaxone disk should be interpreted according to the following three criteria:

1. Susceptible organisms produce zones of 18 mm or greater, indicating that the tested organism is likely to respond to therapy.

2. Organisms that produce zones of 14 to 17 mm are expected to be susceptible if a high dosage (not to exceed 4 gm per day) is used or if the infection is confined to tissues and fluids (e.g., urine) in which high antibiotic levels are attained.

3. Resistant organisms produce zones of 13 mm or less, indicating that other therapy should be selected. Organisms should be tested with the ceftriaxone disk, since ceftriaxone has been shown by *in vitro* tests to be active against certain strains found resistant to cephalosporin class drugs.

Organisms having zones of less than 16 mm around the ceftriaxone disk are not necessarily of intermediate susceptibility or resistant to ceftriaxone.

Standardized procedures require use of control organisms. The 30 mcg ceftriaxone disk should give zone diameters between 29 and 35 mm for *S. aureus* ATCC 25923 and 17 and 23 mm for the reference strains *E. coli* ATCC 25922, *S. aureus* ATCC 25923 and *P. aeruginosa* ATCC 27853, respectively.

DILUTION TECHNIQUES: Based on the pharmacokinetic profile of ceftriaxone, a bacterial isolate may be considered susceptible if the MIC value for ceftriaxone is not more than 16 mcg/ml. Organisms having an MIC value of less than 64 mcg/ml but greater than 16 mcg/ml are expected to be susceptible if a high dosage (not to exceed 4 gm per day) is used or if the infection is confined to tissues and fluids (e.g., urine) in which high antibiotic levels are attained.

E. coli ATCC 25922, *S. aureus* ATCC 25923 and *P. aeruginosa* ATCC 27853 are also the recommended reference strains for controlling ceftriaxone dilution tests. Greater than 95% of MICs for the *E. coli* strain should fall within the range of 0.016 to 0.5 mcg/ml. The range for the *S. aureus* strain should be 1 to 2 mcg/ml, while for the *P. aeruginosa* strain the range should be 8 to 64 mcg/ml.

INDICATIONS AND USAGE: Rocephin is indicated for the treatment of the following infections when caused by susceptible organisms.

LOWER RESPIRATORY TRACT INFECTIONS: caused by *Strep. pneumoniae*, *Streptococcus species* (excluding enterococci), *Staph. aureus*, *H. influenzae*, *H. parainfluenzae*, *Klebsiella species* (including *K. pneumoniae*), *E. coli*, *E. aerogenes*, *Proteus mirabilis* and *Serratia marcescens*.

SKIN AND SKIN STRUCTURE INFECTIONS: caused by *Staph. aureus*, *Staph. epidermidis*, *Streptococcus species* (excluding enterococci), *E. cloacae*, *Klebsiella species* (including *K. pneumoniae*), *Proteus mirabilis* and *Pseudomonas aeruginosa*.

URINARY TRACT INFECTIONS (complicated and uncomplicated): caused by *E. coli*, *Proteus mirabilis*, *Proteus vulgaris*, *M. morganii* and *Klebsiella species* (including *K. pneumoniae*).

UNCOMPLICATED GONORRHOEA (cervical, urethral and rectal): caused by *Neisseria gonorrhoeae*, including both penicillinase and nonpenicillinase-producing strains.

PELVIC INFLAMMATORY DISEASE caused by *N. gonorrhoeae*.

BACTERIAL SEPTICEMIA caused by *Staph. aureus*, *Strep. pneumoniae*, *E. coli*, *H. influenzae* and *K. pneumoniae*.

BONE AND JOINT INFECTIONS caused by *Staph. aureus*, *Strep. pneumoniae*, *Streptococcus species* (excluding enterococci), *E. coli*, *P. mirabilis*, *K. pneumoniae* and *Enterobacter species*.

INTRA-ABDOMINAL INFECTIONS caused by *E. coli* and *K. pneumoniae*.

MENINGITIS caused by *H. influenzae*, *N. meningitidis* and *Strep. pneumoniae*. Ceftriaxone has also been used successfully in a limited number of cases of meningitis and shunt infections caused by *Staph. epidermidis* and *E. coli*.

PROPHYLAXIS: The administration of a single dose of ceftriaxone preoperatively may reduce the incidence of postoperative infections in patients undergoing coronary artery bypass surgery.

Although ceftriaxone has been shown to have been as effective as cefazolin in the prevention of infection following coronary artery bypass surgery, no placebo-controlled trials have been conducted to evaluate any cephalosporin antibiotic in the prevention of infection following coronary artery bypass surgery.

SUSCEPTIBILITY TESTING: Before instituting treatment with Rocephin, appropriate specimens should be obtained for isolation of the causative organism and for determination of its susceptibility to the drug. Therapy may be instituted prior to obtaining results of susceptibility testing.

CONTRAINDICATIONS: Rocephin is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.

WARNINGS: BEFORE THERAPY WITH ROCEPHIN IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS, PENICILLINS OR OTHER DRUGS. THIS PRODUCT SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN SENSITIVE PATIENTS. ANTIBIOTICS SHOULD BE ADMINISTERED WITH CAUTION TO ANY PATIENT WHO HAS DEMONSTRATED SOME FORM OF ALLERGY PARTICULARLY TO DRUGS. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE THE USE OF SUBCUTANEOUS EPINEPHRINE AND OTHER EMERGENCY MEASURES.

Pseudomembranous colitis has been reported with the use of cephalosporins (and other broad spectrum antibiotics); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use.

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Treatment with broad spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis. Cholestyramine and colestipol resins have been shown to bind to the toxin *in vitro*. Mild cases of colitis respond to drug discontinuance alone. Moderate to severe cases should be managed with fluid, electrolyte and protein supplementation as indicated.

When the colitis is not relieved by drug discontinuance or when it is severe, oral vancomycin is the treatment of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should also be considered.

PRECAUTIONS: GENERAL: Although transient elevations of BUN and serum creatinine have been observed at the recommended dosages, the nephrotoxic potential of Rocephin is similar to that of other cephalosporins.

Ceftriaxone is excreted via both biliary and renal excretion (see Clinical Pharmacology). Therefore, patients with renal failure normally require no adjustment in dosage; when usual doses of Rocephin are administered, but concentrations of drug in the serum should be monitored periodically if evidence of accumulation exists, dosage should be decreased accordingly.

Dosage adjustments should not be necessary in patients with hepatic dysfunction; however, in patients with both hepatic dysfunction and significant renal disease, Rocephin dosage should not exceed 2 gm daily without close monitoring of serum concentrations.

Alterations in prothrombin times have occurred rarely in patients treated with Rocephin. Patients with impaired vitamin K synthesis or low vitamin K stores (e.g., chronic hepatic disease and malnutrition) may require monitoring of prothrombin time during Rocephin treatment. Vitamin K administration (10 mg weekly) may be necessary if the prothrombin time is prolonged before or during therapy.

Prolonged use of Rocephin may result in overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken. Rocephin should be prescribed with caution in individuals with a history of gastrointestinal disease, especially colitis.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Carcinogenesis: Considering the maximum duration of treatment and the short-term carcinogenicity studies with ceftriaxone, no animals have not been performed. The maximum duration of animal toxicity studies was six months.

Mutagenesis: Genetic toxicology tests included the Ames test, a micronucleus test and a test for chromosomal aberrations in human lymphocytes cultured *in vitro* with ceftriaxone. Ceftriaxone showed no potential for mutagenic activity in these studies.

Impairment of Fertility: Ceftriaxone produced no impairment of fertility when given intravenously to rats at daily doses up to 586 mg/kg/day approximately 20 times the recommended clinical dose of 2 gm/day.

PREGNANCY: Teratogenic Effects: Pregnancy Category B. Reproductive studies have been performed in mice and rats at doses up to 20 times the usual human dose and have not evidenced any embryotoxicity, fetotoxicity or teratogenicity in primates. No embryotoxicity or teratogenicity was demonstrated at a dose approximately three times the human dose.

There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nonteratogenic Effects: In rats, in the Segment I (fertility and general reproduction) and Segment II (perinatal and postnatal) studies, with intravenously administered ceftriaxone, no adverse effects were noted on various reproductive parameters during gestation and lactation, including postnatal growth, functional behavior and reproductive ability of the offspring, at doses of 586 mg/kg/day or less.

NURSING MOTHERS: Low concentrations of ceftriaxone are excreted in human milk. Caution should be exercised when Rocephin is administered to a nursing woman.

PEDIATRIC USE: Safety and effectiveness of Rocephin in neonates, infants and children have been established for the dosages described in the Dosage and Administration section.

ADVERSE REACTIONS: Rocephin is generally well tolerated in clinical trials. The following adverse reactions, which were considered to be related to Rocephin therapy or of uncertain etiology, were observed:

LOCAL REACTIONS:—pain, induration or tenderness at the site of injection (1%). Less frequently reported (less than 1%) was phlebitis after IV administration.

HYPERSENSITIVITY:—rash (17%). Less frequently reported (less than 1%) were pruritus, fever or chills.

HEMATOLOGIC:—eosinophilia (6%), thrombocytosis (51%) and leukopenia (2%). Less frequently reported (less than 1%) were anemia, leukopenia, lymphopenia, thrombocytopenia and prolongation of the prothrombin time.

GASTROINTESTINAL:—diarrhea (12%). Less frequently reported (less than 1%) were nausea or vomiting and dyspepsia.

HEPATIC:—elevations of SGOT (31%) or SGPT (33%). Less frequently reported (less than 1%) were elevations of alkaline phosphatase and bilirubin.

RENAL:—elevations of the BUN (12%). Less frequently reported (less than 1%) were elevations of creatinine and the presence of casts in the urine.

CENTRAL NERVOUS SYSTEM:—headache or dizziness were reported occasionally (less than 1%).

GENITOURINARY:—moniliasis or vaginitis were reported occasionally (less than 1%).

MISCELLANEOUS:—diaphoresis and flushing were reported occasionally (less than 1%).

Other rarely observed adverse reactions (less than 0.1%) include leukocytosis, lymphocytosis, monocytosis, basophilia, a decrease in the prothrombin time, jaundice, glycosuria, hematuria, bronchospasm, serum sickness, abdominal pain, colitis, flatulence, dyspepsia, palpitations and epistaxis.

DOSEAGE AND ADMINISTRATION: Rocephin may be administered intravenously or intramuscularly. The usual adult daily dose is 1 to 2 gm given once a day (or in equally divided doses twice a day) depending on the type and severity of the infection. The total daily dose should not exceed 4 grams.

For the treatment of serious gonorrheal infections in children, other than meningitis, the recommended total daily dose is 50 to 75 mg/kg/day (not to exceed 2 grams) given in divided doses every 12 hours.

Generally, Rocephin therapy should be continued for at least two days after the signs and symptoms of infection have disappeared. The usual duration is 4 to 14 days; in complicated infections longer therapy may be required.

In the treatment of meningitis, a daily dose of 100 mg/kg (not to exceed 4 grams) given in divided doses every 12 hours, should be administered with or without a loading dose of 75 mg/kg.

For the treatment of uncomplicated gonococcal infections, a single intramuscular dose of 250 mg is recommended.

For preoperative use (surgical prophylaxis), a single dose of 1 gm administered 1/2 to 2 hours before surgery is recommended.

When treating infections caused by *Streptococcus pyogenes*, therapy should be continued for at least ten days.

No dosage adjustment is necessary for patients with impairment of renal or hepatic function, however, blood levels should be monitored in patients with severe renal impairment (e.g., dialysis patients) and in patients with both renal and hepatic dysfunctions.

HOW SUPPLIED: Rocephin (ceftriaxone sodium/Roche) is supplied as a sterile crystalline powder in glass vials and piggyback bottles. The following packages are available:

Vials containing 250 mg equivalent of ceftriaxone: Boxes of 10 (NDC 0004 1962 01)

Vials containing 500 mg equivalent of ceftriaxone: Boxes of 10 (NDC 0004 1963 01)

Vials containing 1 gm equivalent of ceftriaxone: Boxes of 10 (NDC 0004 1964 01)

Piggyback bottles containing 1 gm equivalent of ceftriaxone: Boxes of 10 (NDC 0004 1964 03)

Vials containing 2 gm equivalent of ceftriaxone: Boxes of 10 (NDC 0004 1965 01)

Piggyback bottles containing 2 gm equivalent of ceftriaxone: Boxes of 10 (NDC 0004 1965 03)

Both pharmacy containers containing 10 gm equivalent of ceftriaxone: Boxes of 1 (NDC 0004 1971 01)

NOT FOR DIRECT ADMINISTRATION

Roche Laboratories
Division of Hoffmann-La Roche Inc
Nutley, New Jersey 07110

ROCHE

References:

1. Data on file, Hoffmann-La Roche Inc.
2. Patel IH, Kaplan SA. *Am J Med* 77:17-25, Oct, 1984
3. Richards DM, et al. *Drugs* 27:469-527, 1984
4. Cleeland R, Squires E. *Am J Med* 77:3-11, Oct, 1984
5. Tanner DJ, Nazarian MQ. *Am J Med* 77:104-111, Oct, 1984

133rd Annual Session North Carolina Medical Society

April 29 - May 2, 1987

Pinehurst Hotel and Country Club, Pinehurst, North Carolina

Wednesday, April 29

- 1:00 p.m.- 4:00 Hospital Medical Staffs Section (Crystal Room)
- 2:00 p.m.- 5:00 Registration (West Lobby)
- 2:00 p.m.- 5:00 Public Health & Education Section (Azalea Room)
- 3:00 p.m.- 5:00 Health Insurance Companies and Plans Committee (Pine Room)
- 6:30 p.m.- 8:00 Exhibitors' Reception (West Lawn)

Thursday, April 30

- 7:00 a.m.- 9:00 AMA Delegation Breakfast (Crystal Room)
- 7:00 a.m.-11:00 N.C. Academy of Family Physicians Board Breakfast (Azalea Room)
- 8:00 a.m.- 5:00 Registration (West Lobby)
- 9:00 a.m.- 5:00 Exhibits (North Room, South Room, Dogwood Room, Main Corridor, Ballroom Lobby)
- 9:30 a.m.-12:00 House of Delegates (Cardinal Ballroom)
- 9:30 a.m.- 1:30 N.C. Commission for Health Services (Pine Room)
- 12:00 p.m.- 2:00 Medpac Luncheon (West Lawn)
- 2:00 p.m.- 5:00 Reference Committee I (Cardinal Ballroom)
- 2:00 p.m.- 5:00 Reference Committee II (Azalea Room)
- 2:00 p.m.- 5:00 Reference Committee III (Crystal Room)
- 5:30 p.m.- 7:00 ECU School of Medicine Alumni Reception (West Porch, South End)
- 5:30 p.m.- 7:00 UNC School of Medicine Alumni Reception (West Porch, North End)
- 5:30 p.m.- 7:00 Duke University School of Medicine Alumni Reception (Front Porch, West End)
- 6:00 p.m.- 7:00 Bowman Gray School of Medicine Alumni Reception (Azalea Room Porch)
- 6:00 p.m.- 7:00 Medical College of Virginia Alumni Reception (Room 439)
- 8:30 p.m.-12:00 President's Reception & Dance (Cardinal Ballroom)

Friday, May 1

- 8:00 a.m.- 5:00 Registration (West Lobby)
- 8:00 a.m.- 5:00 Exhibits (North Room, South Room, Dogwood Room, Main Corridor, Ballroom Lobby)
- 8:00 a.m.-11:30 First General Session (Cardinal Ballroom)
- 9:00 a.m.-12:00 Mediation Committee (Carolina Board Room)
- 9:00 a.m.-12:00 Urology Section (Azalea Room)
- 9:00 a.m.-12:00 Psychiatry Section (Magnolia Room)
- 9:00 a.m.-12:00 Allergy & Clinical Immunology Section (Pine Room)
- 11:00 a.m.- 1:00 N.C. Orthopaedic Association Executive Committee (Carolina Board Room)

- 12:00 p.m.- 2:00 Ophthalmology Section Luncheon (Country Club Dining Room)
- 1:00 p.m.- 2:00 N.C. Orthopaedic Association Business Meeting (Pine Room)
- 2:00 p.m.- 5:00 Pediatric Section & Plastic and Reconstructive Surgery Section (Cardinal Ballroom)
- 2:00 p.m.- 5:00 Family Practice Section (Azalea Room)
- 2:00 p.m.- 5:00 Emergency Medicine Section (Magnolia Room)
- 2:00 p.m.- 5:00 Orthopaedic Section (Pine Room)
- 2:00 p.m.- 5:00 Neurology Section (Parlor 129)
- 2:00 p.m.- 5:00 Ophthalmology Section (Country Club Dining Room)
- 2:00 p.m.- 5:00 N.C. Society of Internal Medicine Executive Committee (Merion Villa)
- 2:00 p.m.- 5:00 Obstetrics & Gynecology Section (Mid Pines Resort)
- 5:00 p.m.- 6:30 N.C. Society of Plastic and Reconstructive Surgery Board Meeting (Amherst Room, Holly Inn)
- 5:30 p.m.- 7:00 N.C. Society of Internal Medicine Reception (Merion Villa)
- 7:30 p.m.- 9:30 President's Dinner (Cardinal Ballroom)

Saturday, May 2

- 8:00 a.m.- 3:00 Registration (West Lobby)
- 8:00 a.m.-12:00 Anesthesiology Section (Pine Room)
- 8:00 a.m.-12:00 Radiology Section (South Room); also Sunday May 3, same time
- 9:00 a.m.-12:00 Second General Session (Cardinal Ballroom)
- 9:00 a.m.-12:00 Dermatology Section (Crystal Room)
- 9:00 a.m.-12:00 Otolaryngology & Maxillofacial Surgery Section (Azalea Room)
- 9:00 a.m.-12:00 Resident Physicians Section (Carolina Board Room)
- 9:00 a.m.-12:00 Neurological Surgery Section (Magnolia Room)
- 9:00 a.m.-12:00 Medical Students Section (Dogwood Room)
- 9:00 a.m.-12:00 Pathology Section (North Room)
- 9:00 a.m.-12:00 Surgery Section (Country Club Dining Room)
- 9:00 a.m.-12:00 N.C. Society of Plastic & Reconstructive Surgery General Membership Meeting (Amherst Room, Holly Inn)
- 12:00 p.m.- 2:00 Dermatology Section Luncheon (West Porch, South End)
- 12:00 p.m.- 2:00 New Hanover-Pender County Medical Society Caucus (Parlor 129)
- 12:30 p.m.- 2:00 Pitt County Medical Society Caucus (Carolina Board Room)
- 1:00 p.m.- 2:00 Mecklenburg County Medical Society Caucus (Azalea Room)
- 1:00 p.m.- 2:00 Forsyth-Stokes-Davie County Medical Society Caucus (Magnolia Room)
- 2:00 p.m.- 5:00 House of Delegates (Cardinal Ballroom)
- 7:00 p.m.- 8:00 N.C. Chapter, American College of Radiology Reception (North Room)
- 8:00 p.m.-10:00 N.C. Chapter, American College of Radiology Dinner (South Room)

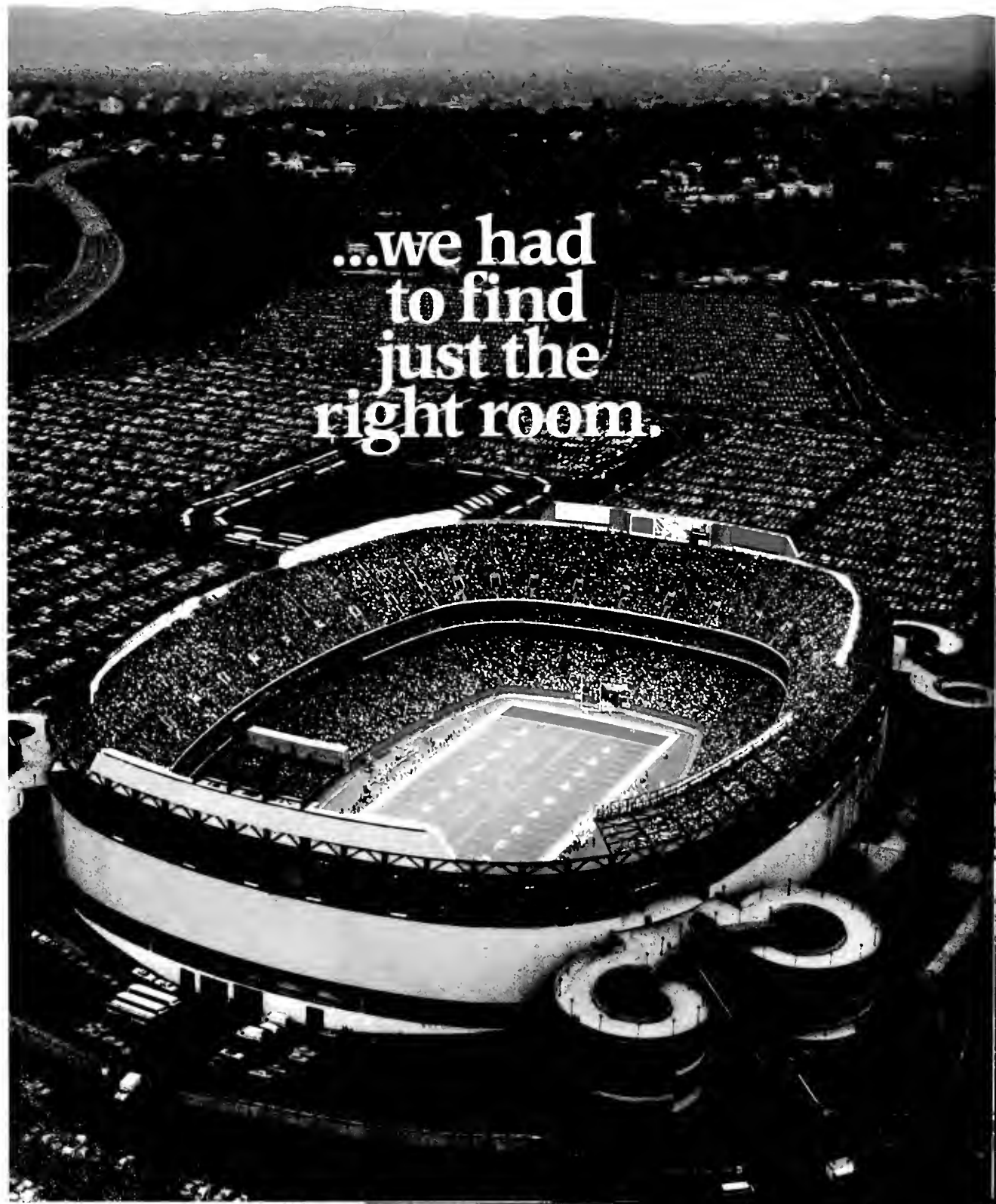
To show you how many
hypertensives stayed on

INDERAL[®] LA
(PROPRANOLOL HCl)

after a major nationwide trial...



**...we had
to find
just the
right room.**



60,073 patients (90%) who started on INDERAL[®] LA stayed on INDERAL LA.^{1*}

Surprising? Not really.

Because most patients on INDERAL LA (propranolol HCl) don't even know it's working.

A recent double-blind, placebo-controlled, crossover study in 138 hypertensive patients² revealed that INDERAL LA has a side effects profile unsurpassed by atenolol or metoprolol — which shows how well-tolerated once-daily INDERAL LA can be.

Sole therapy or concomitant therapy?

Fifty-nine percent of the time, INDERAL LA stood on its own.

The patients in the nationwide compliance trial were no different from yours. Generally when the antihypertensive regimen is complicated, compliance may become a problem. So, the effectiveness of INDERAL LA as once-daily monotherapy is a big plus. Of the remaining hypertensives in the program, 36% were controlled merely with the addition of a diuretic to INDERAL LA.

For the noncompliant patients in your practice, INDERAL LA may well be the answer.

Almost 20,000 of the patients in the nationwide compliance trial were identified as having been noncompliant with their previous antihypertensive therapy. Their physicians reported that 88% showed improved compliance when placed on once-daily INDERAL LA.

Control, comfort, and compliance

ONCE-DAILY
INDERAL[®] LA
(PROPRANOLOL HCl) LONG ACTING
CAPSULES

Like conventional INDERAL Tablets, INDERAL LA should not be used in the presence of congestive heart failure, sinus bradycardia, cardiogenic shock, heart block greater than first degree, and bronchial asthma.

*After a 30-day trial with INDERAL LA, physicians reported that 90% of the patients would remain on INDERAL LA.

The one you know best keeps looking better

Please see next page for brief summary of prescribing information

The one you know best keeps looking better

BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE CIRCULAR)

INDERAL® LA (Long Acting Capsules)

DESCRIPTION. Inderal LA is formulated to provide a sustained release of propranolol hydrochloride. Inderal LA is available as 80 mg, 120 mg, and 160 mg capsules.

CLINICAL PHARMACOLOGY. Inderal LA is a nonselective beta-adrenergic receptor blocking agent possessing a long-acting, nonselective system activity. It specifically competes with beta-adrenergic receptor stimulating agents for available receptor sites. When access to beta-receptor sites is blocked by Inderal LA, the chronotropic, inotropic, and vasodilator responses to beta-adrenergic stimulation are decreased proportionately.

INDERAL LA Capsules (80, 120, and 160 mg) release propranolol HCl at a controlled and predictable rate. Peak blood levels following dosing with Inderal LA occur at about 6 hours and the apparent plasma half-life is about 10 hours. When measured at steady state over a 24-hour period the areas under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of Inderal tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol, resulting from the slower rate of absorption of propranolol. Over a twenty-four (24) hour period, blood levels are fairly constant for about twelve (12) hours then decline exponentially.

INDERAL LA should not be considered a simple mg for mg substitute for conventional propranolol and the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to Inderal LA from conventional propranolol, a possible need for retitration upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, Inderal LA has been therapeutically equivalent to the same mg dose of conventional Inderal, as assessed by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure, and rate pressure product. Inderal LA can provide effective beta block for a 24-hour period.

The mechanism of the antihypertensive effect of Inderal LA has not been established. Among the factors that may be involved in contributing to the antihypertensive action are (1) decreased cardiac output, (2) inhibition of renin release by the kidneys, and (3) diminution of tonic sympathetic nerve outflow from vasomotor centers in the brain. Although total peripheral resistance may increase initially, it readjusts to or below the pretreatment level with chronic use. Effects on plasma volume appear to be minor and somewhat variable. Inderal LA has been shown to cause a small increase in serum potassium concentration when used in the treatment of hypertensive patients.

In angina pectoris, propranolol generally reduces the oxygen requirement of the heart at any given level of effort by blocking the catecholamine-induced increases in the heart rate, systolic blood pressure, and the velocity and extent of myocardial contraction. Propranolol may increase oxygen requirements by increasing left ventricular fiber length, end diastolic pressure and systolic ejection period. The net physiologic effect of beta-adrenergic blockade is usually advantageous and is manifested during exercise by delayed onset of pain and increased work capacity.

In dosages greater than required for beta blockade, Inderal LA also exerts a quinidine-like or anesthetic-like membrane action which affects the cardiac action potential. The significance of the membrane action in the treatment of arrhythmias is uncertain.

The mechanism of the antianginal effect of propranolol has not been established. Beta-adrenergic receptors have been demonstrated in the pial vessels of the brain.

Beta receptor blockade can be useful in conditions in which, because of pathologic or functional changes, sympathetic activity is detrimental to the patient. But there are also situations in which sympathetic stimulation is vital. For example, in patients with severely damaged hearts, adequate ventricular function is maintained by virtue of sympathetic drive which should be preserved in the presence of AV block, greater than first degree, beta blockade may prevent the necessary facilitating effect of sympathetic activity on conduction. Beta blockade results in bronchial constriction by interfering with adrenergic bronchodilation activity which should be preserved in patients subject to bronchospasm.

Propranolol is not significantly dialyzable.

INDICATIONS AND USAGE. **Hypertension:** Inderal LA is indicated in the management of hypertension, it may be used alone or in combination with other antihypertensive agents, particularly a thiazide diuretic. Inderal LA is not indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: Inderal LA is indicated for the long-term management of patients with angina pectoris.

Migraine: Inderal LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: Inderal LA is useful in the management of hypertrophic subaortic stenosis, especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. Inderal LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. Inderal LA is contraindicated in 1) cardiogenic shock, 2) sinus bradycardia and greater than first degree block, 3) bronchial asthma, 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with Inderal.

WARNINGS. **CARDIAC FAILURE.** Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics and the response observed closely, or Inderal should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and in some cases, myocardial infarction, following abrupt discontinuance of Inderal therapy. Therefore, when discontinuance of Inderal is planned, the dosage should be gradually reduced over at least a few weeks, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If Inderal therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute Inderal therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema) — PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. Inderal should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY. The necessity or desirability of withdrawal of beta-blocking therapy prior

to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

INDERAL (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, e.g., dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers. **DIABETES AND HYPOGLYCEMIA.** Beta-adrenergic blockade may prevent the appearance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more difficult to adjust the dosage of insulin.

HYPERTOXICOSIS. Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid function tests. IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case, this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. **General.** Propranolol should be used with caution in patients with impaired hepatic or renal function. Inderal (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that Inderal may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

Clinical Laboratory Tests. Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS. Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if Inderal is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncope, attacks, or orthostatic hypotension.

Carcinogenesis, Mutagenesis, Impairment of Fertility. Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

Pregnancy. Pregnancy Category C. Inderal has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. Inderal should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. Inderal is excreted in human milk. Caution should be exercised when Inderal is administered to a nursing woman.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: bradycardia, congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud type.

Central Nervous System: lightheadedness, mental depression manifested by insomnia, lassitude, weakness, fatigue, reversible mental depression progressing to cataplexy, visual disturbances, hallucinations, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Gastrointestinal: nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: pharyngitis and agranulocytosis, angioedema, dyspnea, laryngospasm and respiratory distress.

Respiratory: bronchospasm.

Hematologic: agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune. In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: alopecia, LE-like reactions, photosensitivity, dry eyes, male impotence, and Raynaud's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

DOSAGE AND ADMINISTRATION. Inderal LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from Inderal tablets to Inderal LA capsules, care should be taken to assure that the desired therapeutic effect is maintained. Inderal LA should not be considered a simple mg for mg substitute for Inderal. Inderal LA has different kinetics and produces lower blood levels. Retitration may be necessary especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION — Dosage must be individualized. The usual initial dosage is 80 mg Inderal LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood-pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily. In some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS — Dosage must be individualized. Starting with 80 mg Inderal LA once daily, dosage should be gradually increased at three to seven day intervals until optimum response is obtained. Although individual patients may respond at any dosage level, the average optimum dosage appears to be 160 mg once daily. In angina pectoris, the value and safety of dosage exceeding 320 mg per day have not been established.

If treatment is to be discontinued, reduce dosage gradually over a period of a few weeks (see WARNINGS).

MIGRAINE — Dosage must be individualized. The initial oral dose is 80 mg Inderal LA once daily. The usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimum migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximum dose, Inderal LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTROPHIC SUBAORTIC STENOSIS — 80-160 mg Inderal LA once daily.

PEDIATRIC DOSAGE — At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

*The appearance of these capsules is a registered trademark of Ayerst Laboratories.

REFERENCES:

1. Inderal LA National Compliance Evaluation Program. Data on file, Ayerst Laboratories.
2. David M. Lang R. J. The relative antihypertensive potency of propranolol, oxprenolol, atenolol, and metoprolol given once daily. *Arch Intern Med* 1985; 145:1321-1323.

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Two Views of a Patient with Progressive Dementia

Introduction

Albert Heyman, M.D. and Lisa Gwyther, M.S.W.

This issue of the *North Carolina Medical Journal* presents two views of a case history of a 47-year-old man who died after a five-year period of progressive cognitive impairment and personality changes. The first account is a traditional medical case report which describes the occurrence of rheumatic fever in childhood, the subsequent development of cardiac and renal disease, and finally death associated with mental deterioration caused by an unusual form of cerebral vascular disease (Hurwitz BJ, et al, p. 182). The second description is by the patient's wife, Myrna Doernberg (p. 187), whose recent book *Stolen Mind*¹ has become popular reading for families participating in the Alzheimer's Disease and Related Disorders Association.²

In her report of her husband's numerous encounters with the medical profession, Mrs. Doernberg shares her perceptive views of family-doctor relationships, particularly the management of patients with early dementia and behavioral abnormalities.

Because of the unusual nature of the patient's illness, Binswanger's disease, which in this case was associated with a number of systemic complications, an early diagnosis was not made. The diagnosis of this illness is now frequently made by new neuro-imaging procedures. But for Mrs. Doernberg it was not so much the lack of a diagnosis as the lack of communication with her husband's physicians that was most disturbing. In her eloquent review of her experiences, it becomes evident that she was not given sufficient opportunity to express her thoughts and experiences relevant

to her husband's illness. Although it was clear to her that her husband could not provide an adequate history, she was often not included in the physician interviews, nor in discussions of the findings of various consultants, psychologists and other professional personnel.

This situation is unfortunately all too frequent in the initial evaluation of patients with early dementia. In many such instances the patient is not aware of his or her own cognitive impairments and the symptoms are often attributed to emotional, marital or environmental stresses. In this particular case, the patient's behavioral changes were thought to be the result of social, domestic or job-related problems. It was only in the later course of the illness that progressive brain damage was revealed by neuropsychological testing. The etiology of the intellectual impairment then became the major diagnostic problem.

Perhaps the most important lesson to be learned from both of these accounts is that the patient's family must have an active role in the diagnostic and therapeutic management of difficult and complex illnesses. Their involvement is particularly important in cases of dementia and other disorders in which the patient's memory and judgment are impaired. Mrs. Doernberg's publications and her continuing efforts to emphasize the family's needs should be appreciated by the medical profession. ■

References

- 1 Doernberg M. *Stolen mind: the slow disappearance of Ray Doernberg*. Chapel Hill: Algonquin Books, 1986.
- 2 For more information on dementing disorders and support groups, call (in NC) 1-800/672-4213 (Duke Alzheimer's Family Support Program).

From the Joseph and Kathleen Bryan Alzheimer's Disease Research Center, Division of Neurology, Duke University Hospital, Durham 27710.

Subcortical Arteriosclerotic Encephalopathy (Binswanger's Disease)

Report of a Case Simulating Psychiatric Disease and Normal Pressure Hydrocephalus

Barrie J. Hurwitz, M.D., Albert Heyman, M.D.,
Peter C. Burger, M.D., and Burton P. Drayer, M.D.

Subcortical arteriosclerotic encephalopathy, or Binswanger's disease, is a chronic, cerebrovascular disorder characterized by ischemia or infarction of the deep white matter of the cerebral hemispheres, sparing the cortex.^{1,2} Until recently, this disorder has been considered to be uncommon. Most of the reports of this illness describe only a few patients who had evidence of hypertension, stroke and progressive dementia.^{3,4} High-resolution computer tomography (CT) and magnetic resonance imaging, however, have shown that the typical radiographic appearance of Binswanger's disease, i.e., multiple lacunar infarcts and ischemic changes in the periventricular cerebral white matter, can be found in patients with other clinical or neurologic manifestations.⁵ Relatively few patients with Binswanger's disease have had autopsy confirmation of their clinical and neuro-imaging findings.^{6,7}

Case Report

The patient, a 47-year-old male architectural designer, was admitted to Duke University Medical Center in July 1983 for evaluation of chronic progressive dementia. At age nine, he had been diagnosed as having rheumatic fever, and at age 19 he had been rejected from the Armed Services because of a cardiac murmur.

Throughout his adolescence and early adulthood the patient complained of shoulder pain, for which he took as many as eight aspirin tablets a day for more than ten years. In his early thirties, he required stronger analgesics and consumed six to eight tablets a day of a variety of such

medications, including Percodan, Motrin, Percocet, Tylox and Indocin. During the three-year period prior to his admission to Duke Hospital, he had been taking six or more tablets of Darvocet each day.

Beginning at about age 30, the patient had frequent cardiac palpitations which were associated with an irregular fast pulse but no loss of consciousness. These attacks of cardiac arrhythmia were brought to the attention of his physicians on admission to his local hospital five months prior to his admission to Duke. At that time his arterial blood pressure was recorded as 130/90 mm Hg. A His bundle electrocardiogram showed an arrhythmia which was not considered to be clinically significant.

At age 46, the patient had been admitted to a Boston hospital with the complaint of peripheral and facial edema. He was found to have severe albuminuria and elevated serum creatinine levels. A renal biopsy showed severe interstitial fibrosis in the medulla and extensive scarring with abundant hyalinosis of the arteries and arterioles. A diagnosis was made of analgesic nephropathy.

In addition to his renal disease and recurrent pre-syncope, the patient had a history of three episodes of transient focal cerebral ischemia. One occurred in 1981 when he noted the sudden onset of right-sided paresthesias. Examination by a neurologist the following day revealed no residual neurologic deficits. His blood pressure was 142/92 mm Hg. The CT scan and electroencephalogram were normal. A history of two other ischemic attacks was later obtained. One had occurred in 1977 and consisted of a 15-minute period of inability to speak. The last episode, in 1982, also consisted of a speech disturbance.

The patient became aware of his mental changes in 1979 when he expressed doubts as to his ability in carrying out his everyday activities. He sought psychiatric help and was enrolled in group therapy. During the next two to three years his employer noted increasing inability to do simple tasks

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such as making a blueprint or telephoning clients. On a family trip to Hawaii in July 1982, the patient lost his baggage, and he was unable to keep track of travel plans or take responsibility for purchasing tickets or making reservations. His attitude and personality changes during this time period were thought to be of a psychiatric nature and he received sporadic counseling.

Psychologic tests in September 1982 showed a WAIS Full-Scale IQ of 96, a Verbal IQ of 113 and Performance IQ of 70. He was admitted to a psychiatric ward for diagnostic evaluation. A CT scan of the brain showed periventricular lucencies surrounding slightly enlarged frontal horns. A diagnosis was made of dementia caused by normal pressure hydrocephalus, and a ventricular-peritoneal shunt was inserted in February 1983. The patient's mental confusion, memory impairment and personality changes, however, continued to progress.

Repeat psychologic testing in May 1983 showed that the WAIS Full-Scale IQ had fallen to 71, Verbal IQ to 84 and Performance IQ to 57. It was then noted that he had difficulty expressing his thoughts and needs. He became increasingly confused in carrying out simple daily tasks and on one occasion attempted to open a can of food with a pencil. He could no longer use a spoon or fork and had difficulty finding the bathroom in his own home. He was unable to dress himself and had to be instructed in taking a shower and brushing his teeth. He often wandered aimlessly about the house or sat and stared uncomprehending at the television screen. The patient developed a bland personality with very few demands, hostility or agitation.

On admission to Duke Hospital, in July 1983, the patient was quiet, cooperative and pleasant. He did not know his age, the day of the week, the month or year. He was unable to remember a name and address after a few minutes and could not count backward from 20 to 1. He could not recall the names of his children or the name of his sister. He was aware of his serious memory loss but did not appear disturbed by this.

Physical examination revealed a Grade III harsh systolic ejection murmur at the apex of the heart and also at the base with faint transmission to the neck. The arterial blood pressure was 168/92 mm Hg on admission to the hospital and ranged from 130/80 to 150/100 mm Hg during his hospital stay. The pulse was regular with occasional extrasystoles. Neurologic examination showed no focal neurologic deficits or abnormal tendon reflexes.

The hematologic findings were normal but the serum creatinine level was 3.2 mg%, and the BUN, 27 mg%. There was a 3+ proteinuria. Roentgenogram of the chest showed moderate cardiomegaly with left ventricular hypertrophy. The electrocardiogram showed sinus bradycardia at a rate of 59 and a prolonged P-R interval of 0.37. There was right bundle branch block with left ventricular hypertrophy and left ventricular strain. Holter monitoring showed the basic rhythm to be first-degree heart block with a rate of 65 to 100 beats per minute. The P-R interval varied and there

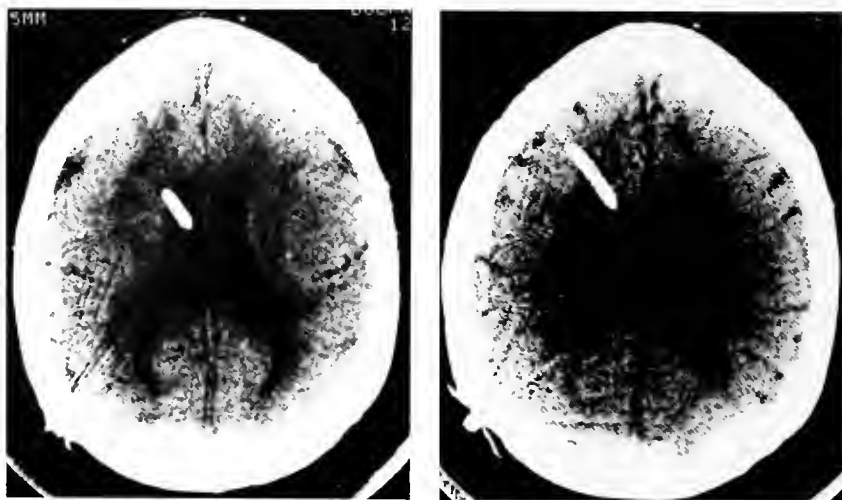
were short sinus pauses. There were long runs of 2:1 second-degree heart block, with ventricular rates of 32 to 40 per minute, lasting up to 40 minutes. There was an occasional escape paroxysmal ventricular contraction. The echocardiogram showed thickening, calcification, and fibrosis of the aortic wall and mitral valve annulus. A pacemaker was implanted to prevent further impairment in cerebral perfusion.

An electroencephalogram showed diffusely slow electrical activity with a frequency of 7 Hz posterior alpha rhythm. Polymorphic intermittent frontal delta activity (1-2 Hz) was present and was thought to be consistent with diffuse encephalopathy. Computer tomography of the brain showed a ventricular catheter in the right frontal horn (figures 1A and 1B, next page). There was mild ventricular dilatation. A confluent area of hypodensity of the cerebral white matter was present in both hemispheres adjacent to the frontal horns, the bodies, and the occipital horns of the lateral ventricles. Focal areas of decreased density were not reported on the antemortem CT reading but were noted in retrospect the following year, when the CT films were compared with slices of the brain made at autopsy. The cortical sulci shown on the CT scans were not abnormally enlarged. The CT findings were considered to be characteristic of subcortical arteriosclerotic leukoencephalopathy or Binswanger's disease.

The patient was discharged from Duke Hospital with a diagnosis of progressive dementia associated with Binswanger's disease. He was also diagnosed as having rheumatic heart disease with moderate aortic stenosis, second-degree atrioventricular block, and azotemia caused by analgesic nephropathy. During the next eight months he showed gradual deterioration in mentation. In March 1984 he was hospitalized following a major motor seizure. Progressive renal impairment was noted but renal dialysis was not advised. Death occurred within a few days.

Postmortem examination showed enlargement of the myocardial wall. The heart weighed 550 gms. The anterior wall of the left lateral myocardium contained a 1 × 1 × 0.5 cm area of old, gray fibrous tissue. There was moderate calcific aortic stenosis. The coronary arteries showed prominent atherosclerosis without complete occlusions or thrombi. The left anterior descending coronary artery was markedly atherosclerotic but not significantly narrowed. The mitral valve and aortic valves were thickened, opaque and rigid. Patchy areas of myocardial fibrosis were present on microscopic examination. The one kidney available from the local prosector weighed 80 gm and showed diffuse granularity of the cortical surface. Marked reduction of the thickness of the medulla was observed on gross examination, and thickening of small arteries on microscopic inspection. The findings were consistent with severe analgesic nephropathy.

The left half of the brain was available for neuropathologic studies. It weighed 610 gm and showed severe atherosclerosis of the distal vertebral artery and the basilar artery without significant stenosis of the lumen. The internal



Figures 1A and 1B. Both photographs show non-enhanced CT scans of the head. A shunt tube is positioned in the right lateral ventricle. The ventricles are slightly enlarged and the cortical sulci are only slightly widened. Multi-focal confluent hypodensities are seen bilaterally in the centrum semiovale, particularly in the areas adjacent to the frontal, body and occipital horns of the ventricles.

carotid artery showed slight atherosclerosis but the middle cerebral and anterior cerebral arteries appeared normal. The cerebral gyri were not atrophic but the ventricles showed moderate dilation.

Small, multiple lacunar infarcts were noted throughout the white matter of the centrum semiovale above the level of the head of the caudate nucleus (figures 2A and 2B). These lesions ranged in diameter from 0.4×0.3 cm to less

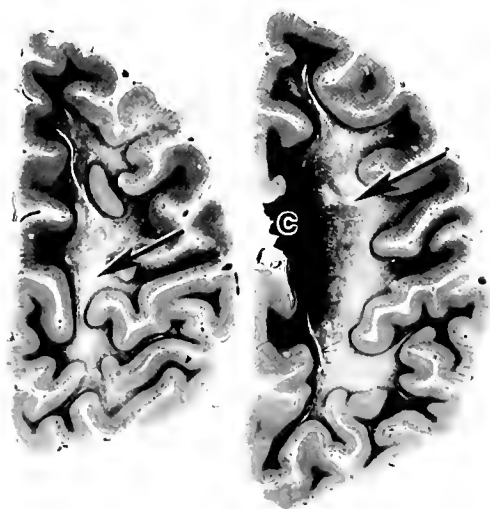


Figure 2A. Two sections of the left hemisphere show diffuse pallor of the centrum semiovale and subcortical lacunar infarcts indicated by arrows. There is a sharp contrast between pale areas of the centrum semiovale and the normal dark staining myelin in the subcortical arcuate fibers and corpus callosum (C). (Hematoxylin and Eosin/Luxol Fast Blue).

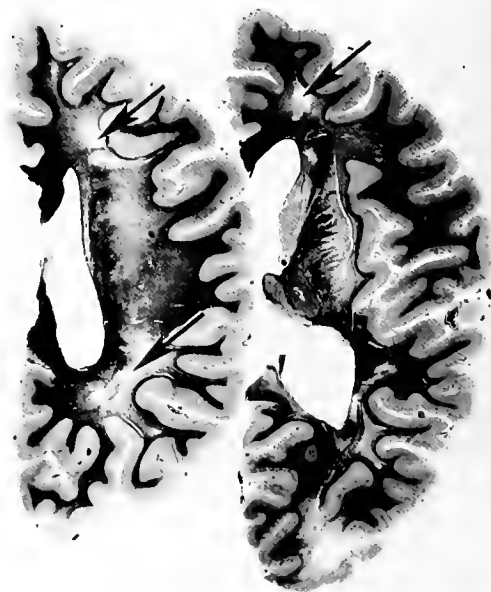


Figure 2B. This section of the left hemisphere cut in the plane of the CT scan in figure 1A shows diffuse pallor of the centrum semiovale and subcortical lacunar infarcts indicated by the arrows. There is, in addition, a small cortical infarct of the occipital tip in this figure. (Hematoxylin and Eosin/Luxol fast Blue).

than a millimeter. Other lacunes were present in the mid-portion of the frontal lobe involving the deep portion of a sulcus, the posterior frontal area as well as the medial occipital lobe. The white matter had a yellow granular appearance and contained vessels with prominent perivascular spaces. No overt lacunes were noted within the basal ganglia or thalamus.

On microscopic examination, the proximal portion of Sommer's sector showed a small focus of loss of neurons and resultant gliosis. No neurofibrillary changes or granulovacuolar degeneration were found. Multiple small lacunar infarcts were scattered within the central semiovale and basal ganglia. Vascular changes consisted of thickening of small arteries, associated with a scant perivascular lymphocytic infiltrate (figure 3). The pallor of the white matter was most striking with sparing of the internal capsule, corpus callosum, and subcortical arcuate fibers (figure 4). This abnormality was diffuse and independent of adjacent lacunes. In the more severe areas there was conspicuous vacuolization in the white matter as well as moderate astrocytosis. Stains of the axis cylinder in these areas disclosed considerable loss of axons with small or absent myelin sheaths.

A comparison was made of the whole-mount, hematoxylin and eosin-stained section of the brain with the CT findings in the same horizontal sections of the brain. The

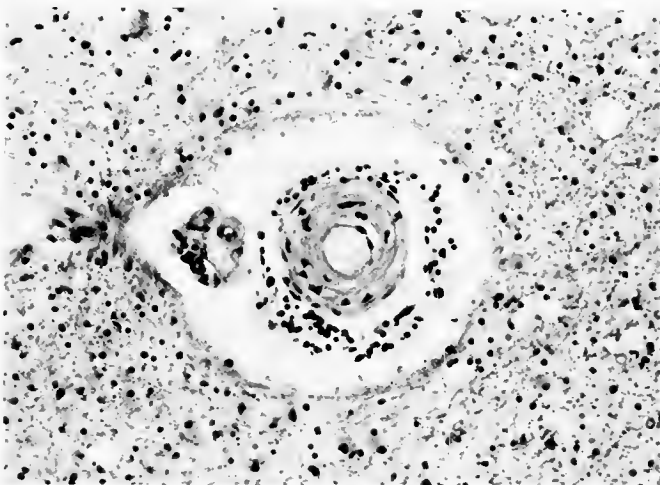


Figure 3. Many of the vessels in the deep white matter and basal ganglia were markedly thickened and surrounded by a few lymphocytes and astrocytes. (Hematoxylin and Eosin/Luxol Fast Blue, $\times 250$).

multiple areas of lacunar infarction in the central semiovale corresponded to focal areas of hypodensity seen in retrospect on the CT scan. The diffuse demyelination noted on the whole-mount sections matched the confluent hypodensities seen on the CT scan. There were, however, many more discrete lacunar infarcts in the tissue whole-mount than could be delineated by the CT scan.

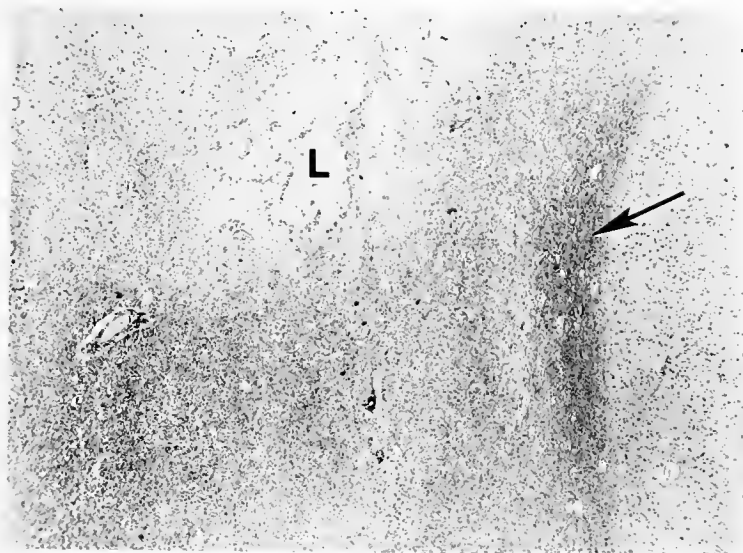


Figure 4. This section of the cerebral cortex shows the underlying subcortical arcuate fibers and centrum semiovale stained for myelin. A lacunar infarct (L) is present in the deep white matter. The pallor of the white matter is in sharp contrast to the darker staining subcortical region indicated by the arrow (Hematoxylin and Eosin/Luxol Fast Blue $\times 25$).

Discussion

This case report calls attention to several clinical, pathological and neuroradiological features of Binswanger's disease which are important in understanding the nature of the disorder. Our patient had behavioral changes and signs of mental impairment of five years' duration without persistent focal neurologic deficits. Although there was a history of several episodes of transient paresthesias in the limbs and speech disturbances, these focal symptoms of cerebral ischemia were overshadowed by the progressive mental changes. For this reason it is understandable that the patient's behavioral symptoms, such as loss of interest and motivation, were attributed to a psychiatric disorder.

It should be emphasized that personality changes and cognitive impairment without localized cerebral manifestations are not unusual in patients with Binswanger's disease. One such patient was reported by one of the authors,⁴ and similar cases have been described by others.⁵ Even in the absence of focal neurological deficits, neuro-imaging procedures (i.e., CT scans and magnetic resonance images) often show ischemic lesions in the cerebral white matter. The pathogenetic mechanism responsible for the behavioral abnormalities and for the loss of cognitive function in these patients is not certain. Some investigators believe that the severe dementia may be caused by the multiple lacunar infarctions; others believe that diffuse edema of the subcortical tissues is responsible for progressive cognitive impairment.^{8,9}

The absence of persistent hypertension in our patient may have been another factor contributing to the delay in making the correct diagnosis. Binswanger's disease is usually associated with moderate or severe hypertension, but cases have been described with normal blood pressure measurements.¹⁰

Although our patient had only an occasional elevation of blood pressure, left ventricular hypertrophy was present at autopsy. The small medullary arteries in both cerebral hemispheres were found to have segmental arterial degeneration characteristic of hypertensive vascular disease. The patient also had valvular heart disease and recurrent cardiac arrhythmia. These conditions may have produced intermittent cerebral ischemia, and perhaps contributed to the development of dementia.

The findings in the patient's later CT scans were characteristic of Binswanger's disease. They consisted of bilateral, symmetrical areas of decreased density of the periventricular white matter and centrum semiovale. Although no lacunar infarcts were observed in the antemortem readings of the CT scans, retrospective examination was thought to show multiple small lacunes throughout the white matter which matched those in the whole brain slices.

Prior to the patient's admission to Duke Medical Center a diagnosis of normal pressure hydrocephalus was made on

the basis of slightly enlarged ventricles and decreased density of the periventricular white matter surrounding the frontal horns. The presence of such hypodense areas in the CT scans of this disorder is believed to be caused by transpendymal flow of spinal fluid from ventricles into white matter. The differential diagnosis between Binswanger's disease and normal pressure hydrocephalus may be difficult. Various criteria have been suggested for the differentiation of the white matter hypodensity in the two illnesses, but in many instances the diagnostic problem is not easily resolved.⁵

In summary, this patient presented a complex array of renal, cardiac, neurological and behavioral symptoms caused by several separate but related diseases. The unusual nature of his illness led to a delay in diagnosis of this uncommon cause for vascular dementia.

The emotional distress of the patient's family resulting from this situation is vividly described by his wife in her book *Stolen Mind*.¹¹ A description of her personal experiences in dealing with this illness follows this article. It provides additional insights into the nature of the disease. ■

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A Family's View of Progressive Dementia

Myrna Doernberg

My husband, Ray, employed as a vice-president of an architectural design firm, did not remember how to execute a perspective drawing. He sat at his drawing board for hours, knowing what he wanted to do, but he was unable to begin. At 46 years of age, he described himself as feeling paralyzed. For the past few months he had become noticeably confused and disoriented when driving. He had problems handling money, he had not been sufficiently able to concentrate to read a book in over a year, and he generally lacked his previous interest in and passion for life.

He had recognized a problem three years earlier, attributed it to midlife changes and sought psychological counseling for a brief period. Gradually, he had delegated responsibilities to me at home and to others at work. Eventually, his job performance was affected so that he was not able to function responsibly. He was asked to take a leave of absence.

The degenerative process was slow and insidious. Subtly, but relentlessly, it was eroding Ray's cognition and affect. No longer were there isolated incidents of forgetfulness, poor judgment, and misunderstood and atypical responses and behaviors. Rather, the frightening changes had affected and disrupted all facets of Ray's daily life, work, and relationships.

Ray was admitted to the psychiatric ward in September 1982. The previous May he had been diagnosed as having analgesic nephritis. This was a result of the aspirin and stronger analgesics he had taken over the years for undiagnosed shoulder pains, following rheumatic fever as a child. This illness had left him with a functional heart murmur which exempted him from the armed services but did not curtail his physical activity.

Although Ray clearly presented symptoms of depression, the depression appeared atypical. During his five weeks in the hospital, an antidepressant was prescribed. A CT scan was taken during hospitalization and a diagnosis was made of metabolic encephalopathy. On discharge from the hospital, we were told that proper nutrition and exercise would help Ray resume a functional life.

Our hope for Ray's recovery was initially quite good. Although there was a gnawing within me that his illness wasn't that simple, I trusted and wanted to believe that we had control over what was happening. The months that followed were difficult. Our expectations were high. Ray

applied for another job, after struggling for two weeks on his resume. I began the process of applying for social security disability. Although we wanted to believe that Ray would be well enough to work, the reality was that he was able to do little. Our comfortable and open style of communicating over the previous 22 years of marriage was now fraught with misunderstanding and confusion.

During the four months that followed Ray's hospitalization, I found little support from the medical community. The hospital psychiatrist saw Ray a few times during that period. Ray reported that they discussed setting goals. He did not feel that he was being helped.

In February 1983 a CT scan indicated that Ray had normal pressure hydrocephalus. We were told that there was only a 25% chance that Ray would improve with surgery. Given no other options, I agreed to the insertion of a ventriculoperitoneal shunt. Ray healed quickly from the surgery, but continued to decline cognitively. Although we had contact with the neurosurgeon who checked the shunt periodically, he did not provide the support we needed.

I knew Ray was deteriorating, but aside from a family physician I met at the Alzheimer's Support Group, there was no follow-through from the physician who had been involved in Ray's case.

Physicians seem to gain satisfaction from patients who respond to treatment, improving and getting well from their care. Ray's case was an enigma to the doctors who initially saw him. He was a young man. He was not getting better. He was deteriorating. There were no answers.

In July 1983, Ray went to Duke University Medical Center. It was there, for the first time, that I was taken aside and asked numerous questions about Ray's medical history, changes in mentation, personality, and functioning. For the first time I felt that the information I provided, along with the psychological testing and other diagnostic procedures, offered the staff a more complete picture of his condition.

After a hospitalization period of two weeks, caused by the unexpected need for a pacemaker, Ray was diagnosed as having subcortical arteriosclerotic encephalopathy or Binswanger's disease. I was told the disease was terminal, but the progression was unknown. Again we were sent home. I knew Ray was to die, but did not know when or how.

During the months that followed, until his death in March of 1984, my emotional support came from the Alzheimer's

Disease and Related Disorders Support Group and friends to whom I reached out. Members of our support group learned from each other, sharing the parts of our souls that our physicians would never know. Losing a loved one to a disease that robs his very essence is probably beyond the awareness of most of the medical community.

I have learned much in retrospect. It is always easier to look back and recognize that a serious problem had been developing. But, sometimes Monday morning quarterbacking pays off.

Diseases that involve impaired cognition do not fit into neat, easily diagnosed categories. Instead, symptoms of dementia reflect many disorders, some treatable. Unlike other conditions in which a specific battery of tests can determine the cause, diseases that affect cognition are not so easily discerned. Consequently, the role of the physician becomes much more investigative and may require a degree of imagination. When a patient presents with atypical symptoms, as Ray did, it seems both practical and feasible that a multidisciplinary team be formed, drawing expertise from the various health sciences. It then becomes possible to explore all options, increasing the chances of an early, accurate diagnosis.

Although it is usually difficult to make an early diagnosis of progressive, irreversible dementia, an accurate diagnosis is crucial. First, if the condition is reversible, early treatment is imperative. Second, early intervention, even for a fatal disease, allows time for the victim to make decisions for the future, before progression of the dementia precludes his or her participation.

Today we know that "senility" is not a normal process of aging. People well into the eighth and ninth decade of life can be productive and independent. Yet, problems still persist in the diagnosis of Alzheimer's disease and other dementing disorders. Too often I hear about elderly patients with symptoms of memory loss who receive a diagnosis of hardening of the arteries without comprehensive testing. "What do you expect?" their family members are told. "She's 80 years old."

Physicians must learn to ask families for background information. Questions about behavioral, personality, and functional changes can help the physician to ascertain the presence of subtle changes that indicate an organic rather than a psychological disturbance.

If the doctors had asked me about Ray's symptoms during his first hospitalization, I could have provided them with a more accurate medical history. Together we could have defined the subtle changes that were taking place. I had much to offer — more than I realized. I knew that Ray was giving inaccurate information. I knew he filled the blanks in his memory in much the same way we do with dreams that we only partially remember. Often he did not understand the question, or remember it long enough to give a response. But I hesitated, not having been invited, to share with the physicians. Ray had become a passive, tentative, confused man. I feared that my speaking for him, correcting him,

would be viewed as a factor in Ray's behavior and illness. Indeed, Ray was seen as weak and dependent whereas I appeared to be strong and aggressive. No one knew, including myself, what had happened to the two of us.

As part of the initial hospital assessment, Ray and I were asked to see a marriage therapist. The therapist felt that even if there was an organic component to Ray's illness, it was in Ray's interest to be passive. Misreading all the subtle, yet present signs, he saw Ray as strong and controlling. He told us that Ray knew that if he didn't function, I would. I believed that. I was vulnerable, misunderstanding the dynamics of what was happening. Frightened and angry by my inability to understand and control what was happening, I was responsive to anyone who attempted to help. An early diagnosis, although difficult to handle, certainly would have avoided the unnecessary pain of attacking our relationship — our greatest strength.

Families of cognitively impaired patients need a kind of support that is, for the most part, not available to us. They suffer in a way that those touched by other terminal diseases do not. They are alone, unable to prepare with their loved one for the end. Rather, they experience what Alzheimer's families come to understand as "the long goodbye" — a disease that takes the self before the body — a disease that robs one of dignity and humanity long before the outer shell no longer functions.

Family members are often at a loss. We are frightened, and often feel abandoned by family and friends. Because of our inability to reach the person we are losing and to make a significant difference in his life, we experience a profound sense of loss of control.

From the family members I have met who endure this living funeral, I have learned that they come to understand and accept the reality of this disease. But they also need support — even if there are no answers, and no effective treatment.

Near the end of Ray's hospitalization at Duke, one of his physicians called me aside one afternoon. We walked to an empty, private area where he asked me to sit down. With just a few minutes of his time, he offered some advice and concern which made me feel he could reach beyond the confines of his medical expertise. The caring perspective that he provided that afternoon gave me additional strength to cope with the uncertain, yet devastating, future we were to face.

I am convinced that the real caring for the patients comes from involvement with the family. Helping the family identify and maintain its own strength most assuredly results in better care for the patient. Working with victims and families of cognitively impaired and terminally ill patients takes time from the physician. Much of that time is needed to offer support, provide a sense of caring, understanding, openness and honesty.

Families have the right to information, guidance, and compassion from physicians. We think physicians have that special ability and knowledge. Physicians who do not have

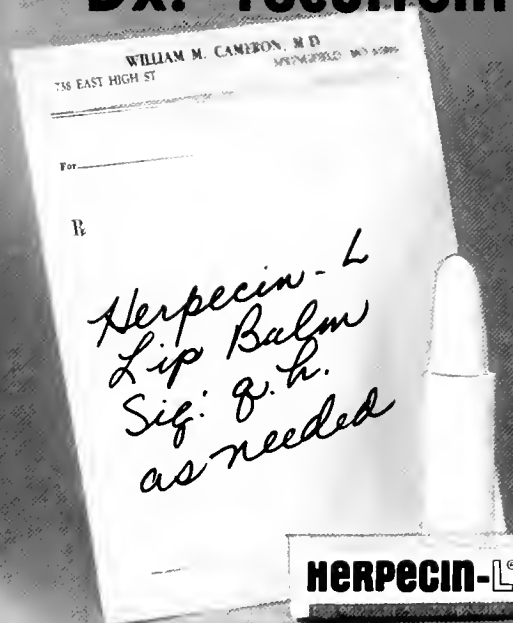
the time to provide for families in this way would do well to refer patients to those who do.

Today there are an estimated two and a half million victims of Alzheimer's disease and related disorders in this country. When their family members are included as incapable victims, the number swells to 15 million. As we enter the twenty-first century with promises of increased longevity, it is incumbent upon the medical community to learn how to care for cognitively impaired patients as well

as their families.

With new technological advances and increased physician awareness, early and more accurate diagnosis may be a future reality. We hope medical treatments and cures will be forthcoming, but in the meantime, families must learn to cope with the devastation that dementia creates. Ultimately, we depend upon a knowledgeable, compassionate, and supportive medical community to respond to these needs. ■

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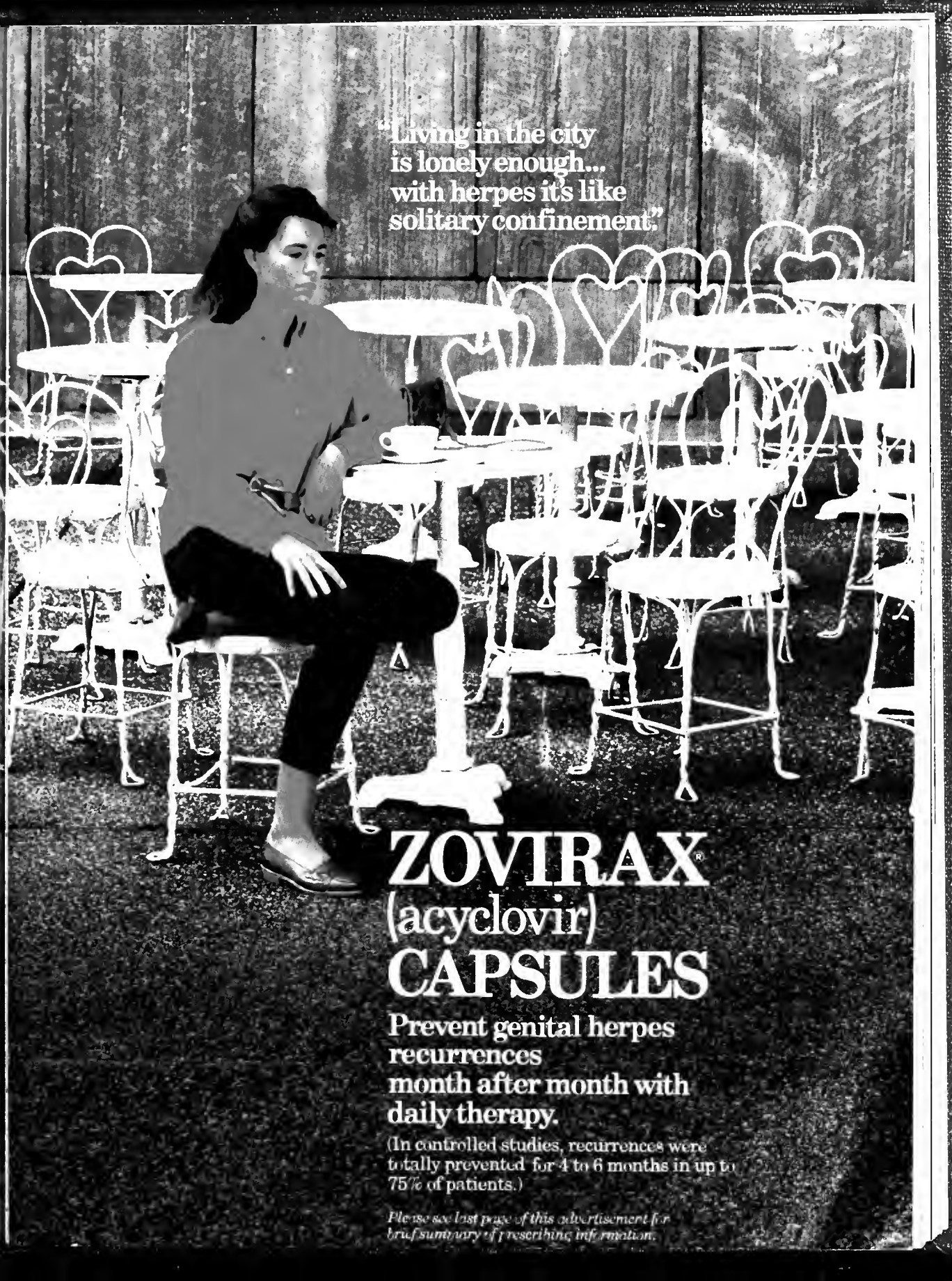
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The severity of disease is variable depending upon the immune status of the patient, the frequency and duration of episodes, and the degree of cutaneous or systemic involvement. These factors should determine patient management, which may include symptomatic support and counseling only, or the institution of specific therapy. The physical, emotional and psychosocial difficulties posed by herpes infections as well as the degree of debilitation, particularly in immunocompromised patients, are unique for each patient, and the physician should determine therapeutic alternatives based on his or her understanding of the individual patient's needs. Thus Zovirax Capsules are not appropriate in treating all genital herpes infections. The following guidelines may be useful in weighing the benefit/risk considerations in specific disease categories:

First Episodes (primary and nonprimary infections — commonly known as initial genital herpes):

Double-blind, placebo-controlled studies have demonstrated that orally administered Zovirax significantly reduced the duration of acute infection (detection of virus in lesions by tissue culture) and lesion healing. The duration of pain and new lesion formation was decreased in some patient groups. The promptness of initiation of therapy and/or the patient's prior exposure to Herpes simplex virus may influence the degree of benefit from therapy. Patients with mild disease may derive less benefit than those with more severe episodes. In patients with extremely severe episodes, in which prostration, central nervous system involvement, urinary retention or inability to take oral medication require hospitalization and more aggressive management, therapy may be best initiated with intravenous Zovirax.

Recurrent Episodes:

Double-blind, placebo-controlled studies in patients with frequent recurrences (6 or more episodes per year) have shown that Zovirax Capsules given for 4 to 6 months prevented or reduced the frequency and/or severity of recurrences in greater than 95% of patients. Clinical recurrences were prevented in 40 to 75% of patients. Some patients experienced increased severity of the first episode following cessation of therapy; the severity of subsequent episodes and the effect on the natural history of the disease are still under study.

The safety and efficacy of orally administered acyclovir in the suppression of frequent episodes of genital herpes have been established only for up to 6 months. Chronic suppressive therapy is most appropriate when, in the judgement of the physician, the benefits of such a regimen outweigh known or potential adverse effects. In general, Zovirax Capsules should not be used for the suppression of recurrent disease in mildly affected patients. Unanswered questions concerning the human relevance of *in vitro* mutagenicity studies and reproductive toxicity studies in animals given very high doses of acyclovir for short periods (see Carcinogenesis, Mutagenesis, Impairment of Fertility) should be borne in mind when designing long-term management for individual patients. Discussion of these issues with patients will provide them the opportunity to weigh the potential for toxicity against the severity of their disease. Thus, this regimen should be considered only for appropriate patients and only for six months until the results of ongoing studies allow a more precise evaluation of the benefit/risk assessment of prolonged therapy.

Limited studies have shown that there are certain patients for whom intermittent short-term treatment of recurrent episodes is effective. This

approach may be more appropriate than a suppressive regimen in patients with infrequent recurrences.

Immunocompromised patients with recurrent herpes infections can be treated with either intermittent or chronic suppressive therapy. Clinically significant resistance, although rare, is more likely to be seen with prolonged or repeated therapy in severely immunocompromised patients with active lesions.

CONTRAINDICATIONS: Zovirax Capsules are contraindicated for patients who develop hypersensitivity or intolerance to the components of the formulation.

WARNINGS: Zovirax Capsules are intended for oral ingestion only.

PRECAUTIONS: General: Zovirax has caused decreased spermatogenesis at high doses in some animals and mutagenesis in some acute studies at high concentrations of drug (see PRECAUTIONS — Carcinogenesis, Mutagenesis, Impairment of Fertility). The recommended dosage and length of treatment should not be exceeded (see DOSAGE AND ADMINISTRATION).

Exposure of Herpes simplex isolates to acyclovir *in vitro* can lead to the emergence of less sensitive viruses. The possibility of the appearance of less sensitive viruses in man must be borne in mind when treating patients. The relationship between the *in vitro* sensitivity of Herpes simplex virus to acyclovir and clinical response to therapy has yet to be established.

Because of the possibility that less sensitive virus may be selected in patients who are receiving acyclovir, all patients should be advised to take particular care to avoid potential transmission of virus if active lesions are present while they are on therapy. In severely immunocompromised patients, the physician should be aware that prolonged or repeated courses of acyclovir may result in selection of resistant viruses which may not fully respond to continued acyclovir therapy.

Drug Interactions: Co-administration of probenecid with intravenous acyclovir has been shown to increase the mean half-life and the area under the concentration-time curve. Urinary excretion and renal clearance were correspondingly reduced.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Acyclovir was tested in lifetime bioassays in rats and mice at single daily doses of 50, 150 and 450 mg/kg given by gavage. There was no statistically significant difference in the incidence of tumors between treated and control animals, nor did acyclovir shorten the latency of tumors. In 2 *in vitro* cell transformation assays, used to provide preliminary assessment of potential oncogenicity in advance of these more definitive life-time bioassays in rodents, conflicting results were obtained. Acyclovir was positive at the highest dose used in one system and the resulting morphologically transformed cells formed tumors when inoculated into immunosuppressed, syngeneic, weanling mice. Acyclovir was negative in another transformation system considered less sensitive.

In acute studies, there was an increase, not statistically significant, in the incidence of chromosomal damage at maximum tolerated parenteral doses of 100 mg/kg acyclovir in rats but not Chinese hamsters; higher doses of 500 and 1000 mg/kg were clastogenic in Chinese hamsters. In addition, no activity was found after 5 days dosing in a dominant lethal study in mice. In 6 of 11 microbial and mammalian cell assays, no evidence of mutagenicity was observed. At 3 loci in a Chinese hamster ovary cell line, the results were inconclusive. In 2 mammalian cell assays (human lymphocytes and L5178Y mouse lymphoma cells *in vitro*), positive responses for mutagenicity and chromosomal damage occurred, but only at concentrations at least 400 times the acyclovir plasma levels achieved in man.

Acyclovir has not been shown to impair fertility or reproduction in mice (450 mg/kg/day, p.o.) or in rats (25 mg/kg/day, a.c.). At 50 mg/kg/day s.c. in the rat, there was a statistically significant increase in post-implantation loss, but no concomitant decrease in litter size. In female rabbits treated subcutaneously with acyclovir subsequent to mating, there was a statistically significant decrease in implantation efficiency but no concomitant decrease in litter size at a dose of 50 mg/kg/day. No effect upon implantation efficiency was observed when the same dose was administered intravenously. In a rat peri- and postnatal study at 50 mg/kg/day a.c., there was a statistically significant decrease in the group mean numbers of corpora lutea, total implantation sites and live fetuses in the F₁ generation. Although not statistically significant,

there was also a dose related decrease in group mean numbers of live fetuses and implantation sites at 12.5 mg/kg/day and 25 mg/kg/day, s.c. The intravenous administration of 100 mg/kg/day, a dose known to cause obstructive nephropathy in rabbits, caused a significant increase in litter resorptions and a corresponding decrease in litter size. However, at a maximum tolerated intravenous dose of 50 mg/kg/day in rabbits, there were no drug-related reproductive effects.

Intraperitoneal doses of 320 or 80 mg/kg/day acyclovir given to rats for 1 and 6 months, respectively, caused testicular atrophy. Testicular atrophy was persistent through the 4-week post-dose recovery phase after 320 mg/kg/day; some evidence of recovery of sperm production was evident 30 days postdose. Intravenous doses of 100 and 200 mg/kg/day acyclovir given to dogs for 31 days caused aspermatogenesis. Testicles were normal in dogs given 50 mg/kg/day, i.v. for one month.

Pregnancy: Teratogenic Effects: Pregnancy Category C. Acyclovir was not teratogenic in the mouse (450 mg/kg/day, p.o.), rat (50 mg/kg/day, s.c.) or rabbit (50 mg/kg/day, s.c. and i.v.). There are no adequate and well-controlled studies in pregnant women. Acyclovir should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. Although acyclovir was not teratogenic in animal studies, the drug's potential for causing chromosome breaks at high concentration should be taken into consideration in making this determination.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Zovirax is administered to a nursing woman. In nursing mothers, consideration should be given to not using acyclovir treatment or discontinuing breastfeeding.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS — Short-Term

Administration: The most frequent adverse reactions reported during clinical trials were nausea and/or vomiting in 8 of 298 patient treatments (2.7%) and headache in 2 of 298 (0.6%). Less frequent adverse reactions, each of which occurred in 1 of 298 patient treatments (0.3%), included diarrhea, dizziness, anorexia, fatigue, edema, skin rash, leg pain, inguinal adenopathy, medication taste and sore throat.

Long-Term Administration: The most frequent adverse reactions reported in studies of daily therapy for 3 to 6 months were headache in 33 of 251 patients (13.1%), diarrhea in 22 of 251 (8.8%), nausea and/or vomiting in 20 of 251 (8.0%), vertigo in 9 of 251 (3.6%), and arthralgia in 9 of 251 (3.6%). Less frequent adverse reactions, each of which occurred in less than 3% of the 251 patients (see number of patients in parentheses), included skin rash (7%), insomnia (4%), fatigue (7%), fever (4%), palpitations (1%), sore throat (2%), superficial thrombophlebitis (1%), muscle cramps (2%), paronychia (1%), menstrual abnormality (4%), acne (3%), lymphadenopathy (2%), irritability (1%), accelerated hair loss (1%), and depression (1%).

DOSAGE AND ADMINISTRATION: Treatment of initial genital herpes: One 200 mg capsule every 4 hours, while awake, for a total of 5 capsules daily for 10 days (total 50 capsules).

Chronic suppressive therapy for recurrent disease: One 200 mg capsule 3 times daily for up to 6 months. Some patients may require more drug, up to one 200 mg capsule 5 times daily for up to 6 months.

Intermittent Therapy: One 200 mg capsule every 4 hours, while awake, for a total of 5 capsules daily for 5 days (total 25 capsules). Therapy should be initiated at the earliest sign or symptom (prodrome) of recurrence.

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*In controlled studies, recurrences were totally prevented for 4 to 6 months in up to 75% of patients.



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"Possibly" effective: as adjunctive therapy in the treatment of peptic ulcer and in the treatment of the irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis.
Final classification of the less-than-effective indications requires further investigation.

Contraindications: Glaucoma; prostatic hypertrophy, benign bladder neck obstruction; hypersensitivity to chlordiazepoxide HCl and/or clidinium Br.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants, and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Physical and psychological dependence rarely reported on recommended doses, but use caution in administering Librium[®] (chlordiazepoxide HCl/Roche) to known addiction-prone individuals or those who might increase dosage; withdrawal symptoms (including convulsions) reported following discontinuation of the drug.

Usage in Pregnancy: Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy. Advise patients to discuss therapy if they intend to or do become pregnant.

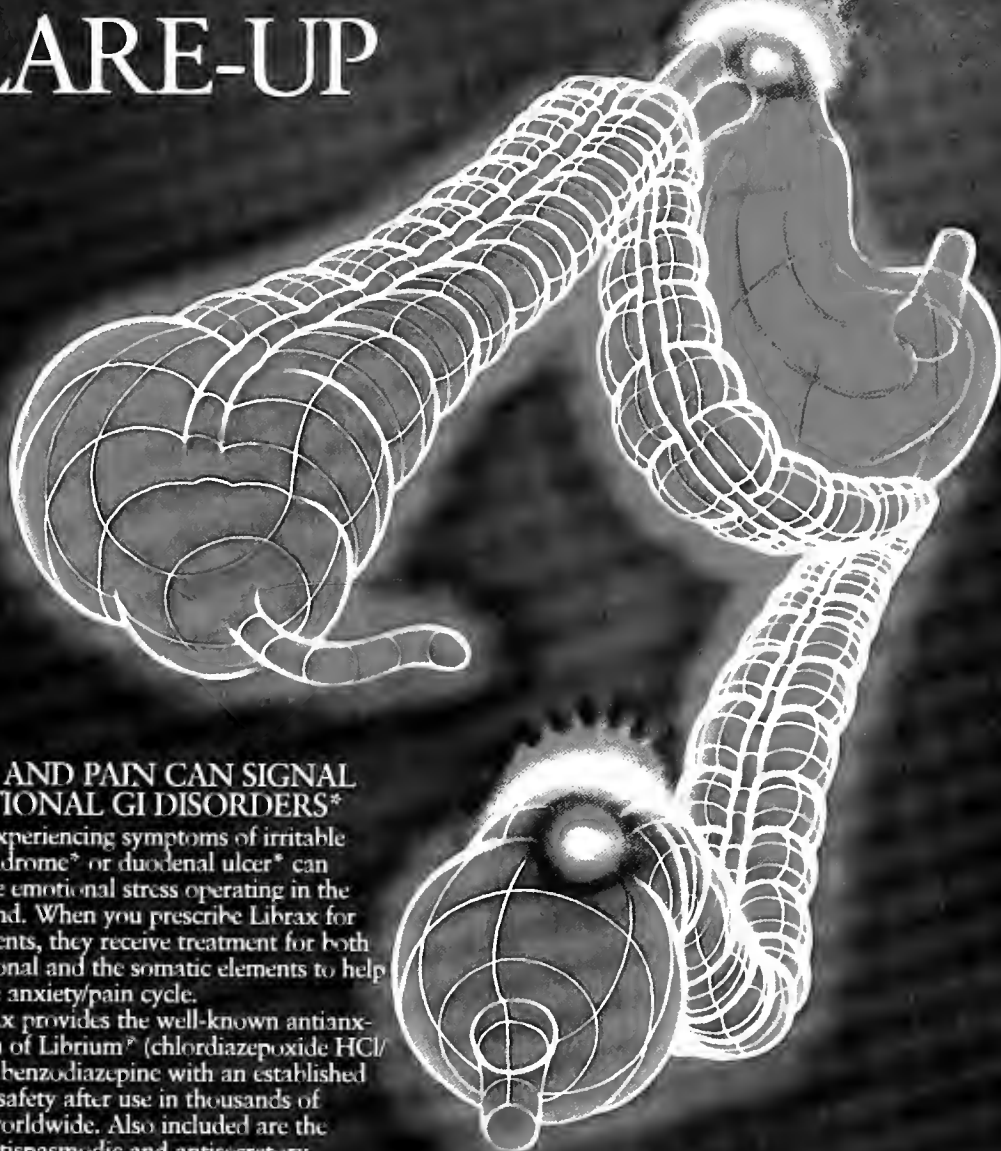
As with all anticholinergics, inhibition of lactation may occur.
Precautions: In elderly and debilitated, limit dosage to smallest effective amount to preclude ataxia, oversedation, confusion (no more than 2 capsules/day initially; increase gradually as needed and tolerated). Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider pharmacology of agents, particularly potentiating drugs such as MAO inhibitors, phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions reported in psychiatric patients. Employ usual precautions in treating anxiety states with evidence of impending depression; suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation reported very rarely in patients receiving the drug and oral anticoagulants; causal relationship not established.

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An Unusual Presentation of Pseudomembranous Colitis

Russell D. Yang, Ph.D., M.D., and
Virginia Byers Kraus, M.D.

Pseudomembranous colitis (PMC) is a distinct clinical entity first described in the late 19th century.¹ Over recent years, PMC has become a serious complication of antibiotic use. We report an unusual case of PMC manifested by perirectal pain, diarrhea and a high peripheral white blood cell count.

The patient, a 49-year-old woman, was hospitalized at the Duke University Medical Center with fever, abdominal pain and volume depletion. She had enjoyed good health except for chronic constipation requiring regular treatment with Docusate Sodium (Colace) and Senokot tablets until developing painful hemorrhoids. She had undergone a routine hemorrhoidectomy without administration of perioperative antibiotics. The patient had tolerated the procedure well except for a postoperative *Escherichia coli* urinary tract infection. Under treatment with Sulfamethoxazole-Trimethoprim (one tablet, double strength, twice a day), she had been discharged from the hospital. Over the next three days, she had developed perirectal pain on defecation, severe watery diarrhea, and abdominal distention.

Upon presentation to the emergency room, she appeared acutely ill with fever, orthostasis, and a white count of 19,600 with a left shift. Granulocytes contained numerous toxic granules on examination of the peripheral smear. Flat plate and upright abdominal roentgenograms revealed edematous folds of bowel with "thumb-printing" features (see figure 1) and the absence of free air. The urinalysis was unremarkable.

Admission physical examination was significant for a markedly distended and diffusely tender abdomen with active bowel sounds. The rectal examination revealed an exquisitely tender rectum with external hemorrhoids and multiple sutures from her recent surgery. There was no perirectal abscess and the rectal vault contained hard stool which was guaiac negative.

The fecal impaction was relieved with enemas. Intravenous Gentamicin was initiated to complete a full seven-day course of therapy for her documented urinary tract infection.

Sulfamethoxazole-Trimethoprim was discontinued. On the second day of admission and five days following her initial dose of Sulfamethoxazole-Trimethoprim, the white blood cell count had climbed to 49,500/mm³. Blood and urine cultures were negative; sputum cultures grew normal flora. The diagnosis of an intra-abdominal abscess was entertained, but a subsequent abdominal computerized tomogram demonstrated only gross, irregular thickening of the colonic wall consistent with diffuse colitis (figure 2, facing page). Oral Vancomycin therapy was started. Stool samples were positive for *Clostridia difficile* toxin at a 1:16 dilution. An irregular mucosa was felt upon rectal examination. Proc-



Figure 1 "Thumb printing" seen on flat plate of the abdomen.

From the Department of Internal Medicine, Box 3211, Duke University Medical Center, Durham 27710.

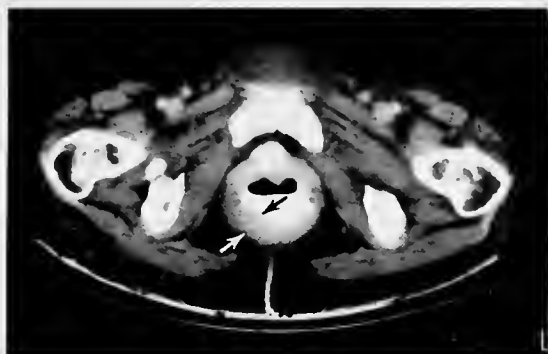


Figure 2. Bowel wall edema.

toscopy was performed with a colonoscope to 10 cm which revealed a diffusely erythematous mucosa with raised yellow plaques which could easily be detached from the mucosa by biopsy forceps (see figure 3). These plaques were pathognomonic of PMC.

Following three days of Vancomycin therapy, the white blood cell count had decreased to $8,700/\text{mm}^3$. Within five days, the abdominal distention and diarrhea had resolved. A total of 14 days of oral Vancomycin (250 mg q 6 hours) was administered. The patient was discharged from the hospital in good condition 19 days following admission.

Discussion

We present this case of antibiotic-associated pseudomembranous colitis because it has both classic roentgenographic features (figures 1 and 2) and endoscopic features (figure 3), as well as atypical findings of constipation and a leukemoid reaction.

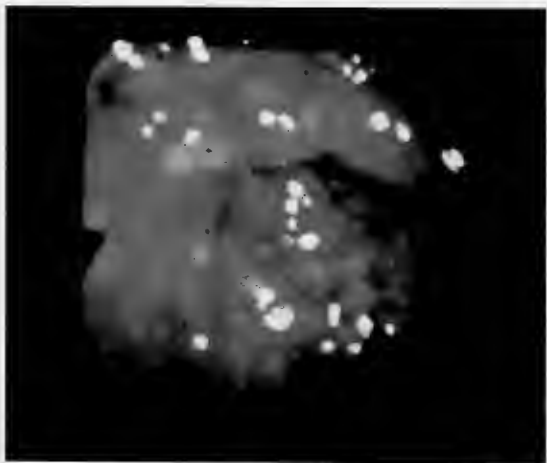


Figure 3. Endoscopic photograph of pseudomembranes. Yellow spots are plaques (white spots are light reflections).

PMC is a dreaded complication of antibiotic administration.¹ It has been reported following administration of virtually every antibiotic. Ampicillin, Clindamycin, and the Cephalosporins are the most frequent offenders. PMC associated with Sulfamethoxazole-Trimethoprim is well documented and occurs commonly, although less frequently.² In this particular case, PMC occurred after only three days of oral Sulfamethoxazole-Trimethoprim therapy. Indeed, Bartlett reports a severe episode of PMC after only one dose of this antibiotic.¹ PMC tends to occur more frequently with oral administration of the antibiotic and is unrelated to dose or duration of treatment.¹ In addition, even if a patient tolerates an antibiotic initially, it is possible for PMC to develop with subsequent administration.

The occurrence of a significant leukemoid reaction to a white blood count of $49,500/\text{mm}^3$ in response to PMC is unusual. Leukocytosis in PMC is variable, but usually averages $15,000/\text{mm}^3$.¹ The highest previously reported white blood cell count is $45,000/\text{mm}^3$.³ This finding reflects the clinical diversity of patients with PMC and emphasizes the need to consider such a diagnosis in the appropriate clinical setting.

Our case demonstrates the classic roentgenographic and proctoscopic findings of PMC. Proctoscopy is the initial diagnostic study of choice in PMC. Nevertheless, examination of plain-films of the abdomen can be quite helpful.^{4,5} Roentgenograms usually reveal gaseous distention of the colon and thickened, edematous folds of bowel wall with "thumb-printing" which are universal in distribution.⁵ Small bowel involvement has also been reported.⁴

These roentgenographic findings are not pathognomonic of PMC, and the acute stages of inflammatory bowel disease (especially the "toxic megacolon" associated with ulcerative colitis), ischemia and infarction of the bowel, and other non-specific forms of colitis⁵ should also be considered. Ulcerative colitis-associated "toxic megacolon" can be distinguished roentgenographically from PMC by its thin colonic walls. Bowel ischemia, like PMC, can be manifested by "thumb-printing," but its distribution is segmental and may involve the small bowel more extensively than would PMC. Bowel infarction differs from PMC in presenting as a generalized ileus.⁵

The mainstay of therapy for antibiotic-associated PMC is withdrawal of the offending agent. For specific therapy, administration of oral Vancomycin has been used most extensively.^{1,6,7} However, the optimal dosage has not been established. It ranges from 125 to 500 mg four times a day.^{6,7} Metronidazole, Bacitracin, and Cholestyramine^{1,8} are also effective, although relapse rates tend to be higher with these medications.

A major disadvantage of treatment with Vancomycin is its high cost — more than \$80 per day. We were able to minimize the expense of administering Vancomycin by saving the unused portion of each 500 mg vial for subsequent doses instead of discarding the excess. ■

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CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

- Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1,243 patients for 0-48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
- Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
- Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
- Acute Hepatic Injury.** In rare instances, significant elevations in enzymes such as alkaline phosphatase, CPK, LDH, SGOT, SGPT, and other symptoms consistent with acute hepatic injury have been noted. These reactions have been reversible upon discontinuation of drug therapy. The relationship to CARDIZEM is uncertain in most cases, but probable in some. (See PRECAUTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic

function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS.)

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in *in vitro* bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy, Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. Diltiazem is excreted in human milk. One report suggests that concentrations in breast milk may approximate serum levels. If use of CARDIZEM is deemed essential, an alternative method of infant feeding should be instituted.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded. In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy. The following represent occurrences observed in clinical studies which can be at least reasonably asso-

ciated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences as well as their frequency of presentation are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%). In addition, the following events were reported infrequently (less than 1%):

Cardiovascular	Angina, arrhythmia, AV block (first degree), AV block (second or third degree — see conduction warning), bradycardia, congestive heart failure, flushing, hypotension, palpitations, syncope
Nervous System	Amnesia, gait abnormality, hallucinations, insomnia, nervousness, paresthesia, personality change, somnolence, tremor, trismus
Gastrointestinal	Anorexia, constipation, diarrhea, dyspepsia, dyspepsia, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH (see hepatic warnings), vomiting, weight increase
Dermatologic	Pelechiae, pruritus, photosensitivity, urticaria
Other	Amblyopia, dyspnea, epistaxis, eye irritation, hyperglycemia, nasal congestion, nocturia, osteoarthralgia, pain, polyuria, sexual difficulties

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: alopecia, gingival hyperplasia, erythema multiforme, and leukopenia. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established. Issued 7/86
See complete Professional Use Information before prescribing.

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NORTH CAROLINA MEDICAL JOURNAL

For Patients

VOLUME 48 / NUMBER 4 / APRIL 1987

Fire Fighters in North Carolina In-Line-Of-Duty Deaths, 1972-1985

LUCY FORT, R.N., AND PATRICIA D. GRIGGS, R.N.

The tragedy starts when a pot of beans is accidentally left to cook during church. A neighbor sees the smoke, and the fire department responds.

The fire fighters make entry and aggressively search for the fire and its victims as they have done so many times before. Then the unthinkable occurs: a flash of fire, the sound of a crashing roof, cries for help, one or all signalling that a fire fighter is in trouble.

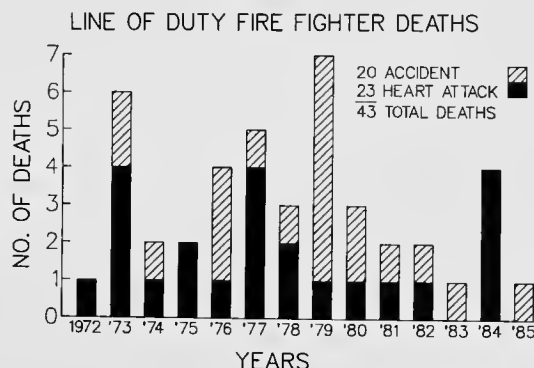
Fire fighting is the nation's most dangerous occupation. Each year, nationwide, there are about 140 deaths reported as caused by fire fighting activities. In North Carolina, there were 43 reported deaths of fire fighters in the line of duty from 1972 through 1985. The causes of death were heart attack, vehicle accidents, and other kinds of accidents (figure 1).

Twenty-three deaths were attributed to coronary heart disease. This represents the largest cause of death (54%) in the entire group. Of these 23 fire fighters, two had medical histories indicating high blood pressure, two had had previous myocardial infarctions (heart attacks), one had undergone coronary bypass surgery, and one had a history of "heart problems." It is important to note that a large majority of those who suffered heart attack deaths

had no reported previous symptoms of heart disease. In most studies, the incidence of sudden death as the initial symptom of coronary heart disease is about 30%. The fact that the figure is higher in this group of fire fighters may be a function of special stresses that are part of fire fighting activities.

Most people associate myocardial infarction with the 50 and above age group, but approximately 33% of the fire fighters who died from heart attack were younger than 49 (figure 2, next page). Three of the victims were between 35 and 39 years of age; four were between the ages of 40 and 49 years; five were between 50 and 59

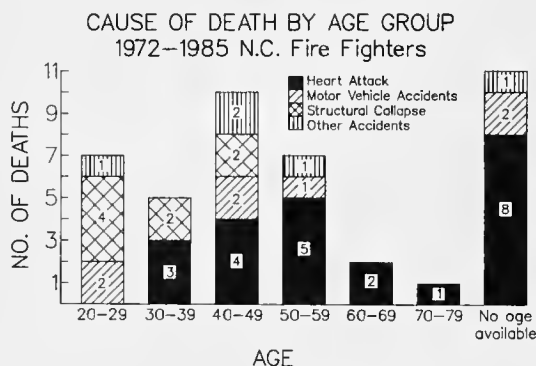
Figure 1



From Orange County Emergency Services, Orange County Court House, Hillsborough 27278.

years of age; two were between 60 and 69; and one was older than 70. Unfortunately, ages were unavailable for eight of the heart attack victims.

Figure 2



Extreme Exertion and Myocardial Infarction

One case involved a 41-year-old assistant chief with a history of high blood pressure who was in charge of activities at a cotton mill fire. He stayed in the mill for long periods of time directing the efforts of fire fighters, pulling hoses and doing inspections. After the fire was out, the assistant chief returned home but complained of a heavy sensation in his chest. He was put into a private car where he collapsed and died on the way to the hospital.

In another case, a 35-year-old fire fighter answered an alarm to a restaurant fire. He carried the hose from the truck and directed a stream of water on the fire while holding the hose above his head. He and another fire fighter took turns doing this job. He complained of pains in his chest and inability to breathe. After the fire, he returned home but continued to complain of chest pains and shortness of breath. He evidently decided not to seek medical care. Finally, after eight days, he was admitted to the hospital. He died 13 days after the fire from complications of a myocardial infarction.

A 52-year-old career fire fighter was dispatched on a winter day to a residential structure fire. The smoke was heavy, filling the area from two feet above the floor to the ceiling. He did not use self-contained breathing apparatus. Shortly after the fire was suppressed, he walked to a neighboring house to interview witnesses. Immediately upon entering, he complained of shortness of breath. He collapsed and later died. This man had experienced heart problems for 10 years and had taken medication regularly for these problems.

A 56-year-old retiree with a history of heart problems joined a volunteer fire department with the assigned duty

of pump operator. A pump operator stays by the truck and operates the pumping valves. This day he received a fire alarm for a brush fire. Finding upon arrival that another fire fighter was operating the pump, he began pulling a one-inch hose from the right side of the truck around the front of the truck and across the street. He had pulled the hose approximately 30 feet out when another fire fighter began to assist him. Together, they pulled approximately 100 feet of hose. Within a few minutes, the second fire fighter felt a tug on the hose and turned to discover that his colleague had fallen to the ground dead. He had suffered a heart attack.

Myocardial infarctions are the end result of a disease called arteriosclerosis, or hardening of the arteries. This disease is a process of deposition of fat and scar in artery walls. The result is obstruction of normal blood flow and damage to organs requiring that blood flow. In the case of the heart, the obstruction is in the coronary arteries. The reduction of blood flow results in weakening or death of the heart's muscle. Arteriosclerotic coronary heart disease leading to heart attack is the most common killer of all Americans, not just fire fighters. However, on-duty fire fighters are probably especially susceptible to having sudden cardiac events — myocardial infarction and sudden death — because the tremendous energy expended in fighting fire greatly increases the need of the heart's muscle for oxygen-carrying blood. It is possible for people to reduce the risk of developing arteriosclerosis and the associated risk of heart attack by reducing known risk factors such as high blood cholesterol, high blood pressure, cigarette smoking and physical inactivity.

Deaths from Motor Vehicle Accidents

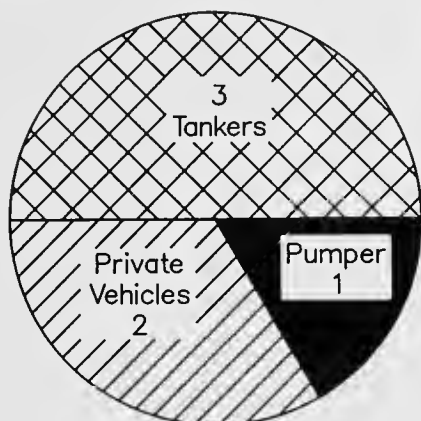
There were 20 fire fighter deaths in North Carolina due to accidents during our study period, constituting the other major group of cases. Motor vehicle accidents accounted for seven of these deaths. Three of the victims were driving filled tankers to the fire scene when they lost control of the vehicles (figure 3, facing page). In one case, the victim was thrown out and the tanker overturned onto him. In the other two cases, the drivers lost control and ran into trees. In another fire apparatus accident, the driver lost control of a pumper during a heavy rainstorm.

Two of the motor vehicle accidents involved fire fighters who were driving private vehicles to a fire. One of the victims died when his pickup truck was struck by a truck loaded with lumber. Another victim drowned after he lost control on a curve and his truck plunged into a river. Finally, a fire fighter sustained massive head injuries when he was struck by a vehicle while directing traffic at a fire scene.

The relatively high number of accidents involving loaded tankers deserves special comment. These vehicles are

inherently dangerous because the liquid load can shift rapidly and with great force. Some fire service tankers are especially dangerous because they are built with too few baffles. Many such vehicles were converted for fire department use. Finally, of course, the use of these vehicles in North Carolina is almost always on rural roads.

Figure 3



DEATHS BY TYPE OF VEHICLE
1972 — 1985

This set of circumstances is probably responsible for a disproportionate number of accidents and is a reason for the fire service leadership to promote special training and educational programs for personnel who operate tankers.

Accidents During Fire Fighting Operations

Structure fires accounted for eight accidental deaths. On May 25, 1979, five people, including four fire fighters, were killed when a two-story burning building suddenly exploded, burying them under brick and cement. These people were all outside the structure when the explosion occurred. The subsequent investigation indicated that an arsonist had placed a highly explosive liquid propellant in the building.

One fire fighter died of burns following a probable back-draft explosion. This fire fighter was one of two who entered a building to extinguish small fires set by radiant heat from a nearby burning building. They were clothed fully in canvas duck protective clothing and were using self-contained breathing apparatus. Both fire fighters suffered extensive burns, although their clothing did not ignite.

Another fire fighter died when a church steeple collapsed, trapping him in the burning church. Several fire

fighters were operating hand lines inside the church in an effort to gain access to the fire in the balcony. During this process, the officer-in-charge noticed instability in the steeple and called for immediate evacuation. Before the crew was clear of the building, the support for the steeple gave way and the steeple collapsed. One fire fighter was trapped and died of massive injuries, one suffered a fracture of a leg, and a third was overcome by smoke. This tragedy highlights the extreme hazard presented by heavy structures (or appliances such as air conditioning units) situated above fire-involved areas of burning buildings.

A fall through the roof into a burning building caused the death of a 27-year-old career fire fighter. He was reported to have stepped onto a soft area of roof over an area of intense attic fire. This incident should reinforce standard operating procedures that require routine use of roof ladders.

Another fire fighter was trapped in the basement of a burning building. He was evidently operating on a hand line with two other fire fighters when he became separated. Shortly thereafter, the fire became intense, and it was impossible to reach him in time to rescue him. He was using full protective clothing, including self-contained breathing apparatus.

Miscellaneous Accidents

In addition to fire or rescue-related accidents, there were several in-line-of-duty deaths that were unrelated to such activities. One fire fighter died from injuries suffered in a fall from a tree he was trimming in the station yard. Another was electrocuted while installing a fire extinguisher on a boat. The fire extinguisher had been sold as part of a fund-raising project for the department.

Finally, there was a fire fighter who drowned while assisting in the search for a body. Although this review is limited to deaths of fire fighters, we would like to note that at least three rescue squad members have drowned in North Carolina under similar circumstances during this 14-year period.

Observations and Recommendations

The most common cause of service-related death among North Carolina's fire fighters is heart attack. This is true at the national level as well. While heart attack is also the most common mortal disease of all Americans, there is reason to believe that the risk for fire fighters is greater because of the level of exertion and stress associated with fighting fire. In any case, the high numbers of fire fighters affected by heart disease warrant a major effort on the part of the fire service community to identify fire fighters with known heart disease and provide them with

appropriate protection from the stresses of fighting fire. Furthermore, there is ample need for efforts to reduce the known risk factors for heart disease among young fire fighters.

A second important observation from this review is that water tanker accidents were disproportionate in number. The safe operation of tankers should be emphasized in training programs, and standard procedures governing tanker operation on the highways should be adopted and enforced by every rural fire department.

Finally, deaths during major structure fires have occurred with unfortunate frequency in this country over the years; and North Carolina is not immune to these tragedies. The lessons learned from our experiences highlight basic safety principles that should be observed at every fire. However, it is also clear that aggressive,

interior attacks on fires in large commercial or public buildings necessarily involve a significant risk to the lives of fire fighters. ■

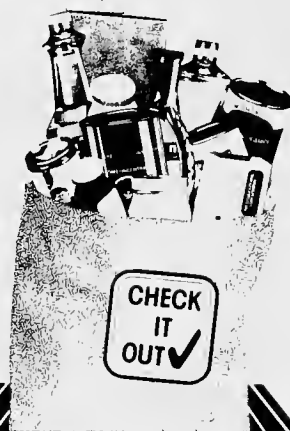
Acknowledgment

The authors express special appreciation to Mrs. Clara Pittman, Director of the North Carolina Firemen's and Rescue Squad Worker's Pension Fund, Department of the State Auditor.

Reference

- 1 This information was acquired from the records of the North Carolina Firemen's and Rescue Squad Workers' Pension Fund.

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— A message from this magazine and the Food and Drug Administration

Drug Solution Among High School Students

RICHARD D. ADELMAN, M.D.

The use and abuse of alcohol and other drugs is a problem of great concern to the medical community. The American Academy of Pediatrics task force recognizes drug and alcohol abuse as a "major area of concern and activity for the organization."¹ Among the young, especially teenagers, substance abuse harms physical health, psychological health, social health, and personal health.

Physical health is affected through increased morbidity from acute and chronic illnesses and increased morbidity and mortality from motor vehicle accidents and other accidents.² Teenagers suffer an estimated 8,000 deaths per year from alcohol-related highway accidents.³ Psychological health problems can result from a change in the sense of well-being. The social health suffers in diminishment of the social effectiveness and ability to accomplish individual tasks. Probably most affected by drug intake is the personal health, which is the adolescent's realization of his or her individual potential.

Four Years of Surveys

In order to establish whether a drug or alcohol problem exists in the high school population of Wake County, and to define the extent of the problem, Drug Action of Wake County, Inc., has commissioned surveys in local high schools.⁴ These surveys have been done annually, beginning in 1983. They show that 50% of the students in the tenth to twelfth grades are moderate to heavy drinkers of alcohol, 25% are light drinkers, and only 25% surveyed stated that they did not drink alcohol.

Over 50% of the students surveyed used marijuana or hashish. The use of cocaine in various forms has been increasing each year, and the use of other drugs — inhalants, hallucinogens, stimulants, barbiturates, tranquilizers, heroin, and others — is all too common.

After establishing the existence of the problem, we should take the important next step, I felt, of asking the

individuals involved for possible solutions. Their suggested options would be more easily accepted than those passed down from other sources, and would have a better chance of solving the drug and alcohol problem. In searching the literature, no study could be found⁵ which asked high school students, their parents, their teachers and administrators what they thought it would take to resolve the immense problem. To address this need, the North Raleigh Rotary Club, under my supervision, developed a new survey instrument: the Drug Action Survey. This survey is unique in enlisting these formerly overlooked people as its participants.

The Drug Action Survey

In November, 1986, the Drug Action Survey was distributed to the students, parents of the students, and administrators at Millbrook High School in Raleigh. Millbrook High School students come from middle-class families in the north Raleigh area primarily. Of the 2,325 students, 84.9% are white and 15.1% minority races, mainly black.⁶ Responses were received from 504 freshmen, 552 sophomores, 489 juniors, and 478 seniors, totaling 2,023 students. In addition, 443 parents and 86 teachers and administrators responded to the survey.

First, respondents were asked if they agreed that a problem existed. Eighty-six percent of students, 97% of parents, and 94% of teachers and administrators agreed that the problem of alcohol and drug abuse existed among the high school students.

Next the participants were asked specifically about alcohol, then marijuana, and then other drugs. When asked who would be most helpful in counseling the students about the alcohol problem, the students responding favored student (peer) counselors. The parents and the administration favored "drug action" (adult) counselors. Least favored among all groups were the existing school counselors and parent counselors. Very few of the responders from any group preferred that school counselors or parents be involved in alcohol problem counseling. The students and the administration favored group as opposed to individual counseling, whereas the parents

From Capital Family Medicine, P.A., 3320 Executive Drive, Suite 214, Raleigh 27609.

viewed group and individual counseling as equally favorable.

When asked about school programs that might deal with alcohol problems, all favored a chapter of Alcoholics Anonymous for teens, with Students Against Drunk Driving (SADD) close behind. Concerning penalties on those who abuse alcohol, all groups favored mandatory programs of counseling, and every group's least favored options were expulsion and suspension.

Marijuana, cocaine, and other drugs were not treated in the same manner as alcohol by the students. Instead of favoring peer student counselors for these drugs, all groups felt that the drug action counselors would be best to treat this problem. When asked which programs would be best, the students and administration were evenly divided between Drug Education School and Narcotics Anonymous, whereas the parents were very strongly in favor of Drug Education School. All groups felt that the penalties should begin with mandatory programs of counseling. The second most favored penalty was a special school for drug users. Again, expulsion and suspension were seen by all groups as least helpful.

The students, parents, and administration were asked their advice on how best to administer information and educate students about the dangers and penalties of drug use. All groups agreed that speakers would be the best approach, with seminars and course time related to the problem the second and third best approaches. Posters, pamphlets, and brochures were not thought to be of much help for this problem.

For education aimed specifically at preventing and solving the drug problem, students again felt speakers would be the most helpful, whereas the parents and administrators favored seminars. The students felt that television would be a very worthwhile form of education. Only a few of the student respondents recommended school counselors, pamphlets, or brochures.

The last item on the survey was an open-ended request for additional suggestions for solving the drug problem. Many of the answers were very lengthy and well thought out. Some conclusions from these will be drawn in the next section. A brief sampling of these responses follows in an appendix.

Discussion

Drugs are a major problem in high schools throughout the nation. Teenagers are extremely vulnerable to the influence of drugs. The U.S. Department of Education states that students who use marijuana regularly are twice as likely as their classmates to have grade averages in the D or F range, and students who use drugs are twice as likely to drop out before graduation from high school.⁷ An awareness of the problem is the first step in resolving the problem. Fortunately, the first step seems to have been taken, as the great majority of high school students

agree that the problem needs to be addressed.

Established risk factors for drug and alcohol abuse include low self-esteem, poor relationship with parents, depression, lack of religious commitment, parental drug use, peer drug use, and sensation-seeking.⁸ Students at Millbrook High School state that drugs become a problem in the absence of love. The students do not want parents or the school administration to get on a "soapbox" and "preach." They want parents to set limits, to show they care, and to show their love for their children.

Due to the immaturity and developmental changes taking place during adolescence, a typical teenager needs an extra demonstration of love and concern from parents. The parent needs to lead through strength, not weakness. The adolescent needs this strength to help build his or her future. One student writes ". . . Some parents don't realize that a hug and 'I love you' would do wonders where ignoring the child is often the common result." To solve the problems of the youth, one has to understand the youth. The solution comes with "thinking like teenagers" instead of "thinking like adults."

Peer pressure contributes to the drug problem. Peer pressure does not cause the drug problem, even though many students would like to blame their weakness on a convenient excuse. Putting all the drug users in a school of their own will not solve the drug problem. Expelling drug users and suspending drug users does not solve the problem. A better solution might be to make it "hip to be square" or "cool to say no." Speakers to whom the students can relate without feeling preached at might bring a better result. Counselors to whom the students can relate, whether peers or trained specialists, are more likely to have an impact than others.

Fear of negative consequences can help curtail drug use.³ Limits must be set for the students and these limits must be enforced. Necessary security must be present to prevent the sale and use of drugs in the school restrooms. The easier it is to obtain drugs, the more drugs will be used. Adolescents use drugs because drugs are readily available, provide a quick and easy way to feel good, possibly aid in gaining peer acceptance,⁹ and enable one to temporarily escape life pressures.

Parents wish to have more information on the subject of drugs, their effects, and how to recognize their use. They wish more information on the metamorphosis of adolescence. The parents express a desire for more education enabling them to better communicate with their children. They do not wish to be their children's bodyguards or their friends, but loving parents. The family is thought to be so important that it may be the most enduring factor in prevention and intervention in drug and alcohol abuse.

The school administration recognizes the problem and is eager to be involved in all programs to help resolve the problem. They express the wish that action be taken as soon as possible.

Recommendations

As a result of this survey the following recommendations are made:

- 1 Establish student support groups with trained peer counselors.
- 2 Hire a confidential school counselor specifically trained to deal with drug-related problems.
- 3 Ensure programs in school to enhance self esteem, life skills, and decision making.
- 4 Enforce a drug free environment in school and at school activities.
- 5 Establish parent support groups to maintain a drug free environment.
- 6 Secure speakers to educate students and parents on the dangers of alcohol and drugs.
- 7 Support parenting workshops.

Summary

To solve the problem, there must be an awareness of the problem; there must be a coordinated effort between teenagers and adults to prevent problems and resolve those that exist; and there must be negative consequences to help prevent use and to curtail the availability of drugs. Positive actions and attitudes on the part of the community, families, and the young people, with open communication, will lead us down the right path to resolution of the problem. More action needs to be taken to clarify different approaches and to assess the results of programs. ■

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Appendix: A selection of written comments from survey respondents

Student comments

"Maybe if parents would quit saying 'not my child' and face up to the fact that their child has a problem with drugs then the road to rehab is within reaching distance. Parents, some parents, don't realize that a hug and an 'I love you' would do wonders where ignoring the child is often the common result. Parents are right when they say 'don't take drugs.' But how many parents say this but don't actually enforce it?"

"People who do drugs and/or alcohol often have problems that are very serious to them. They need love and support, not punishment. Many adults seem to forget what it's like to be a teenager. We have problems that are important to us. We need someone who will listen, not someone who wants to get on his 'soapbox' . . ."

"The problem isn't in the schools — it's at the parties. And if you people would get smart enough you'd realize that. You aren't thinking like teenagers — you're thinking like adults."

"There is a serious misunderstanding of the drug problem. It's not peer pressure that causes people to start taking drugs (alcohol is a drug). It is clearly a matter of personal weakness. . . . What a double standard we're living when we see thousands of beer commercials a week, somebody thinks one 5-second "don't drink and drive" announcement will change things. Who are they trying to kid? . . ."

"School counselors are of no help simply because the student who's using needs someone he can open up to who is very experienced in this field. Either a drug counselor or recovering addict."

"Peer counseling ought to be a class open to anyone who would like to take it. We need a lot of people (kid counselors) to go to the younger schools and tell them about the abuse of drugs. They don't want to hear it from a parent or counselor, but from someone they might look up to and understand."

Parent comments

"We are still No. 1 role models and if enough of us walk a straight line, it may not be so square to be doing the right things."

"Teens often 'get on their parents' nerves' — so what do they do? ESCAPE — go out on foot or in someone else's car and get blown away. How many parents really understand the metamorphosis from childhood to adult?? Teenagers go overboard trying to emulate the adults they love and respect so much."

"Parents need to be made aware that drugs are not a school problem; they are a problem of society. The community at large has to change its attitude regarding 'good ole boys and beer.'"

"We are at fault for the behavior of our young people because we are too busy or don't show we care."

"Encourage local TV stations to take alcohol advertising off TV. It encourages teenagers to try it."

"Every effort should be made to entice young people to participate in some school related activity such as music, sports, newspaper or whatever but it would give them a feeling of belonging."

Teacher comments

"Take action now! Students are killing themselves and ruining their lives. I see kids staring off into space every day! Information is the key!"

"Mandatory parent counseling for parents of users. Students will not take as valid info lectures by school counselors, parents, or teachers who do not have 'credentials,' i.e., personal experience with the problems of drug abuse. The problem of alcohol as a drug must be addressed — not only with the student population but with their parents."

"I am a parent and a teacher and believe that parents should be more responsible for their children's actions. If a student is on drugs, parents should directly be accountable by law for their children. Parents would then do a better job disciplining in the home."

"The first line of defense is in the home. The time, effort and money must be centered on getting parents aware of, and realistic about, the alcohol and drug problem. Most parents are only willing to admit the problem exists on a societal level, but few REALLY BELIEVE IT IS THEIR KID. . . . We are simply ignoring the obvious truth — most drinking and some drug use begins in the seventh grade." ■

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Radiology and Surgery in the Treatment of the Complications of Acute Pancreatitis

Herbert J. Proctor, M.D., F.A.C.S., John A. Schwartz, M.D., Robert Rutledge, M.D., and Mathew A. Mauro, M.D.

Prior to the development of interventional radiology, the role of radiology in the treatment of acute pancreatitis was limited to providing images which were the basis for others to make therapeutic decisions. Historically, operative intervention by surgeons had little impact on the early care of acute pancreatitis. Ranson^{1,2} was among the first to clarify the management of acute pancreatitis by developing predictors which indicated patients most likely to sustain morbidity and/or mortality (table 1). Peritoneal lavage as described by Ranson³ was a treatment modality designed to alter morbidity and mortality. His findings were that mortality for pancreatitis was not changed, simply the time and mode of exit. Patients were living long enough to develop one of five possible complications of acute pancreatitis: pseudocyst, infected pseudocyst, pancreatic abscess, pancreatic necrosis, or infected pancreatic necrosis. Interventional radiology and/or surgery now had the potential of favorably affecting the outcome.

The necessity for surgical drainage of pus, débridement of necrotic tissue, and internal drainage of pseudocysts was unchallenged until recent advances in percutaneous catheter drainage techniques. Although the value of surgery has recently been confirmed by Warshaw,⁴ the timing of surgery is less clear. This is in part due to difficulties with the definition of infected pancreatic pseudocyst vs pancreatic abscess, the role of percutaneous drainage vs operative drainage of pseudocysts, infected pseudocysts, and pancreatic abscesses, and finally the difficulty in differentiation by computed tomography (CT) between necrotic pancreas,

infected necrotic pancreas, and pancreatic phlegmon.⁵

As a result of recent experience on our service (HP), we have come to visualize the progress of a patient with acute pancreatitis as depicted in figure 1 (next page), with the patient passing through the stages of diagnosis, documentation of the degree of severity using Ranson's criteria, deciding on the advisability of lavage, and choosing from among several therapeutic modalities. To validate the appropriateness of this progression sequence, a retrospective review was undertaken.

Patient Population

Group I

During the period 1976-1985, there were 410 admissions (291 patients) to the North Carolina Memorial Hospital for episodes of acute pancreatitis. Fifty-seven patients accounted for 176 admissions. Thirty-three of these patients developed a pseudocyst.

Table 1

Predictors which indicate patients most likely to sustain morbidity and mortality. Ranson.¹

Laboratory Data at Admission

age > 55
wbc > 16000
glucose > 200 mg %
LDH > 350
SGOT > 250

Changes During Initial 48 Hours

Hct fall > 10
BUN rise > 5
Ca < 8 mg %
Base deficit > 4 mEq/l
Est. fluid sequestration > 6000 ml
pO₂ < 60 mmHg

From the Departments of Surgery and Radiology, University of North Carolina School of Medicine, Chapel Hill. Correspondence/reprints: H.J. Proctor, M.D., Department of Surgery, University of North Carolina School of Medicine, Burnett-Womack Clinical Sciences Building 229H, Chapel Hill 27514. This paper was presented at the 20th Annual Meeting, Pancreas Club, May 19, 1986.

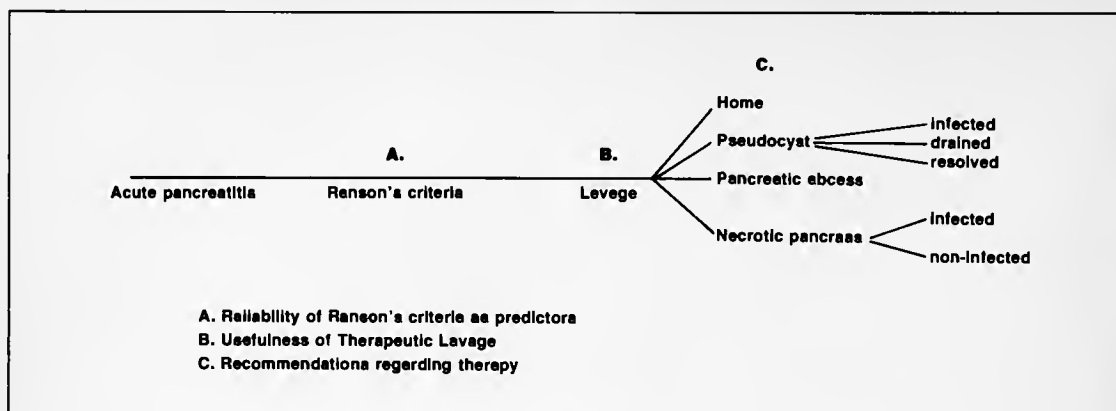


Figure 1. Flow chart illustrating pertinent decision points in diagnosis and treatment of acute pancreatitis.

Group II

During this same period, 123 patients were admitted with the diagnosis of pancreatic pseudocyst, having undergone their initial care for acute pancreatitis elsewhere. With these patients and the 33 patients from Group I who developed a pseudocyst, the total available for outcome study was 156 patients with pancreatic pseudocyst.

Data relating to Group I are expressed in terms of numbers of admissions; data relating to Group II are expressed in terms of numbers of patients. The numbers of admissions, patients and their grouping are summarized in figure 2.

Results

Group I

There were 182 male and 109 female patients, ranging in age from four to 102 years (mean 43.2 years). Multiple admissions (2-10) for pancreatitis were noted in 57 patients for a total of 176 admissions. The remaining 234 patients had isolated episodes of acute pancreatitis. The presumed etiology of pancreatitis and characteristics of the patient population are shown in table 2. Overall, the mean age for male patients (42.8 years) and female patients (44.1 years)

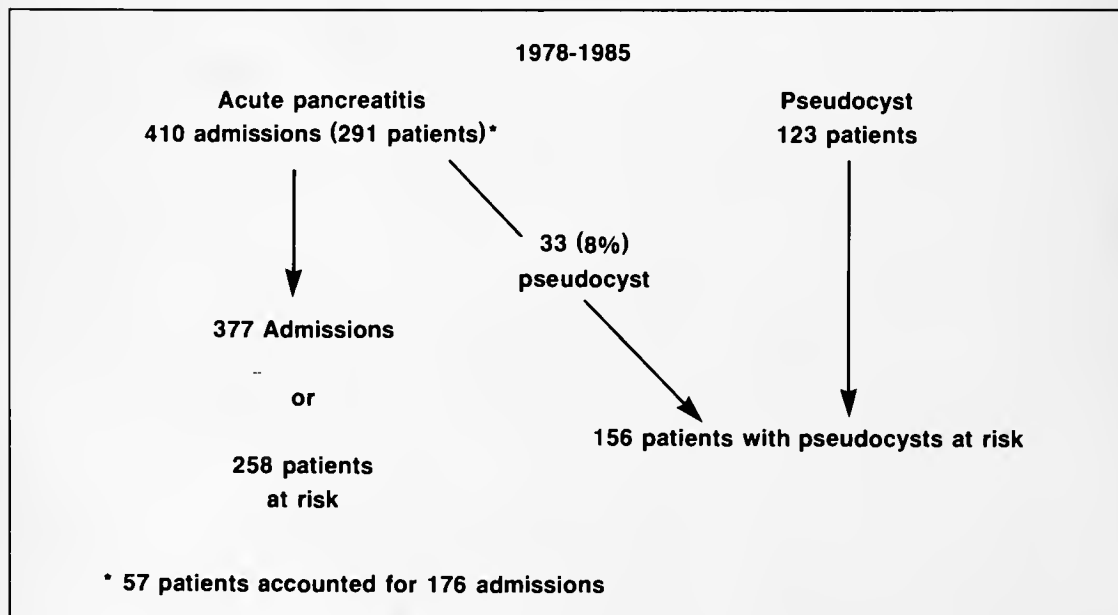


Figure 2. Schematic breakdown of patients and their allocation to treatment groups.

Table 2

Sex and etiology of Group I patients.

	Male 272 (67%)		Female 135 (33%)
Alcohol	80.3%	p<.001	40.5%
Biliary	12.6%	p<.001	30.6%
Other	7.1%	p<.001	28.9%

presenting with pancreatitis was not different. However, patients with alcohol-related diseases were more likely to be male ($p<.001$) and younger (mean age 40.5 years) than those with disease associated with gallstones, who tended to be female and somewhat older ($p<.0005$, mean age 54.4 years).

The admitting serum amylase concentration was greater when biliary tract disease was the etiology of pancreatitis ($1874 \text{ mg/dl} \pm 1856$) as compared to alcoholic pancreatitis ($580 \text{ mg/dl} \pm 650$), $p<.0005$. Other than suggesting a biliary versus alcoholic etiology of pancreatitis, serum amylase levels were of no value in predicting treatment outcome or course of disease.

The prognostic value of Ranson's criteria was confirmed by our data (figure 3). The mortality rates for episodes of acute pancreatitis were significantly increased ($p<.001$) with progressive disease severity as determined by the number of positive Ranson's signs.

The contention³ that peritoneal lavage was indicated to deter early mortality in acute pancreatitis until the later stages of pancreatic necrosis, abscess, or pseudocyst development was not supported by our observations. Although no patient in this series was lavaged, all 31 mortalities occurred after the development of complications (phase C, figure 1).

All patients (9/9) in whom CT was incorrectly interpreted as showing a pancreatic phlegmon died and were found to have infected, necrotic pancreases at autopsy. In comparison, there was a 42% (12/42) mortality for operative débridement of necrotic infected pancreas correctly diagnosed by CT, and 0% mortality in ten patients explored for CT evidence of necrotic pancreas who were found at laparotomy to have only inflammation. Ten additional non-operative patients died, after resolution of pancreatic inflammation, of pulmonary embolus (2), pneumonia (2), gastrointestinal bleeding (4), and myocardial infarction (2).

Group II

The average age was 44 years with a range of four to 69 years. There were 120 male and 36 female patients. In the majority of patients the diagnosis was made using computerized axial tomography or ultrasound, with ultrasound being slightly more common. The average length of symptoms prior to treatment was six months. The cause of pseudocyst, as in the pancreatitis patients in Group I, was overwhelmingly due to alcohol abuse (81%).

The mode of treatment and results of therapy for the patients with pseudocyst are listed in table 3. It should be

Table 3

Mortality and morbidity of various therapies for 156 pancreatic pseudocysts.

	No.	156 Pseudocysts		% Morbidity
		% Total	% Mortality	
Observed	23	15	0	0
Surgical external drainage	16	10	5	65
Percutaneous external drainage	15	9	0	15
Internal drainage	102	65	0	31

noted that if a pseudocyst did not resolve under observation, some form of interventional therapy was recommended and the patient outcome reported under that therapeutic group. Thus the 5% morbidity and 0% mortality reported for observation represent a selected population of patients and gives a falsely optimistic picture.

The most common complications of external drainage of an uninfected pseudocyst were persistent fistula (31%) and infection (25%). Thus internal drainage as performed in the majority of patients (table 3) seems preferable inasmuch as the 31% morbidity incurred was of short duration compared to the long-term problems of managing a persistent (greater than three months) pancreatic fistula which required additional surgery to correct.

The type of operative procedure in each patient involved a certain amount of variability depending upon the surgeon and the year in which the patient was treated. Selection of the operative procedure was made on the following basis: cystogastrostomy was selected for patients with cysts located immediately beneath the stomach; cystojejunostomy was selected for patients with cysts in the head of the pancreas opposing the duodenal sweep; pancreatectomy was selected for patients with an obstructed pancreatic duct, extensive pancreatitis or multiple cysts in the tail of the pancreas; observation was selected for patients with small cysts or a short duration of symptoms; marsupialization or

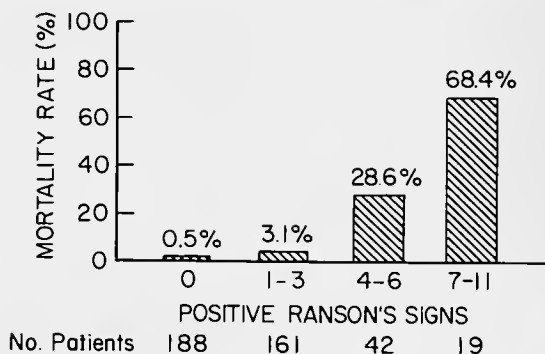


Figure 3. Progressively greater mortality is noted with increasing number of positive Ranson's criteria.

cysts or a short duration of symptoms; marsupialization or external operative drainage were selected for patients who were acutely ill and had immature cyst walls.

The incidence of complications in patients undergoing surgical external drainage was 65%, much higher than in the other groups. Thus the combined (operative and percutaneous) complication and mortality rate was much greater for external drainage than for internal drainage.

Patients' results were classified as Good, Fair, or Poor. Patients were classified as having "good" results if they had returned to work, had no further pain or only mild pain not requiring narcotics, and had no recurrence of their pseudocyst. The result was classified as "fair" if the patient required continued use of pain medication with control of pain and had no further hospitalization or operation. A "poor" result was defined as requiring re-operation or re-hospitalization or involving continued severe pain requiring narcotics. Patients undergoing different kinds of internal drainage, including cystogastrostomy, cystojejunostomy, pancreatectomy, and cystoduodenostomy, had very similar results: 59% good, 25% fair, and 16% poor. Patients undergoing external drainage had poorer long-term results than patients undergoing other types of therapy. Only 20% of patients had good long-term results after external operative drainage.

There were 18 peripancreatic collections of pus. In this study, we did not distinguish between an infected pancreatic pseudocyst and a pancreatic abscess (see discussion). Six collections were drained surgically; 12 were drained percutaneously. All resolved without mortality or significant morbidity related to the manner of drainage.

Discussion

The exocrine pancreas secretes into the gut on demand some 20 proteins necessary for digestion. Autodigestion is prevented by a variety of safeguards. Proteins, lipase, co-lipase, phospholipase A, and proteolytic agents probably account for the edema, tissue destruction, fat necrosis, and other metabolic disorders and eventual mortality in the severely ill patients. In our study, the clinical presentation of abdominal pain, nausea and vomiting, and an elevated serum and/or a urine amylase established the diagnosis, although some of the most severe cases had normal serum amylases, presumably on the basis of near total pancreatic destruction. Beyond that, the concentration of serum amylase had little prognostic significance other than to indicate, if elevated, continued pancreatic inflammation.

Our study confirmed the value of Ranson's criteria. We agree that special attention is needed for patients with more than three criteria positive, in view of the 28.6% mortality noted in this group. We would recommend a computed tomographic study in all such patients. Computed tomography is currently the radiologic examination of choice in

patients suspected of having complicated acute pancreatitis. CT is reliable in identifying and locating fluid collections and complicated inflammatory masses associated with acute pancreatitis. CT evaluates the entire abdomen, including the deep pelvic recesses, giving an accurate appraisal of the full extent of the inflammatory process.

The concept of introducing a dialysis catheter in the infraumbilical position to dilute out noxious substances seems attractive in theory but has been challenged by a number of recent studies.⁶⁻⁸ Mayer, et al⁸ have recently completed a multicenter study in which 46 patients were assigned to the control group and 45 to the lavage group. There were 13 deaths (28%) and 16 patients with major complications (35%) in the control group compared with 12 deaths (27%) and 17 patients with major complications (38%) in the lavage group. Lavage did not appear to modify the length of survival, or the incidence of peripancreatic collections (pseudocysts and abscesses). Mayer did find the use of lavage to be helpful in establishing the diagnosis of acute fulminant pancreatitis, correctly identifying 90% of the patients, most of whom died or underwent pancreatic necrosis.⁷

Ballardin et al in a study aimed primarily at determining the usefulness of aprotinin in the lavage fluid incidentally also found no improvement in results with lavage without aprotinin.⁹ Our data do not support the use of lavage since all of the deaths among our patients occurred as a result of the late sequelae of pancreatitis, not in the early phases where lavage has reportedly had its greatest efficacy. Whether the frequency of complications (necrosis, abscess, pseudocysts) would have been lowered by lavage we cannot say; however, our incidence of these appears to be consistent with the findings of others.^{4,10}

This leads to two questions: what is the best way to follow patients who have acute pancreatitis; and when complications develop, what is appropriate management? Fluid can be identified quite reliably on CT scan by virtue of location or density. Collections appropriate for percutaneous drainage include pseudocysts, infected pseudocysts, and pancreatic abscesses. Recent reports suggest at least 80% of patients with pseudocysts and 70% of patients with pancreatic abscesses can be cured with non-operative percutaneous drainage.¹¹⁻¹³ Patients with pancreatic abscesses not cured by catheter drainage are often temporarily improved, allowing more elective definitive treatment.

Our data indicate that liquid pus, regardless of etiology (infected pseudocyst vs pancreatic abscess), is best handled by external drainage. In view of the success and low morbidity, percutaneous catheter drainage is recommended. It is of secondary importance whether the pus originates in a secondarily infected pseudocyst or derives from liquefaction of infected pancreas. A preliminary needle aspiration and culture is useful in establishing the diagnosis, but may not always be accurate. Surgical drainage should be reserved for (a) a percutaneous route involving other organs or the pleural space; (b) pus too thick to drain using a percutaneously placed catheter; (c) associated conditions such as

ascitic fluid with high amylase content which may be evacuated surgically in conjunction with drainage; and (d) presence of necrotic tissue, or at least a situation in which it cannot be reliably ruled out.

A pancreatic phlegmon represents diffuse swelling of the pancreas secondary to edema and inflammatory cell infiltration, and it is not of drainable consistency. Foci of necrosis may be present as well. On CT, phlegmons most commonly appear as irregular masses with attenuation values greater than water. However, appearances are variable and there are no pathognomonic morphologic or density appearances. Peripancreatic extension is not uncommon. Devitalized glandular tissue and fluid are the main components of a necrotic gland. The early CT appearances of pancreatic necrosis are often indistinguishable from a phlegmon within the pancreatic bed. With time the overall internal density of the necrotic gland decreases. The entire gland is typically affected, being diffusely enlarged but maintaining a pancreatoform configuration. A thick soft-tissue rim may be seen surrounding the lower density necrotic gland.

Percutaneous needle aspiration is the only quick and reliable way of diagnosing a superinfected necrotic gland. Percutaneous aspiration should only be performed when a safe access route can be identified. Such a route can often be found using CT guidance. The absence of culture-positive

results does not rule out infection, and careful review of the overall clinical course is necessary. While fluid and pus have been successfully drained percutaneously, the residual semisolid material within a necrotic gland often requires surgical evacuation. In such cases, percutaneous drainage may be of benefit as a temporizing measure in a critically ill patient allowing later surgical débridement in a more stable setting.

The surgical exposure we favor is through a transverse upper abdominal incision as described by Bolooki, et al.¹⁴ and Bradley, et al.^{15,16} The lesser sac is entered through the greater omentum and the pancreas is exposed (figure 4). The necrotic pancreas may be either black in the case of hemorrhagic pancreatitis or putty gray if significant hemorrhage has not occurred. In either event, the necrotic material is gently debrided using finger fracture with sharp dissection used only sparingly. The adjacent mesenteric and splenic vessels are extremely friable as is the remaining inflamed but viable pancreas, and care must be taken not to create hemorrhage. One of the operative deaths in this series died with massive uncontrollable bleeding and secondary coagulopathy. A cholecystostomy tube is placed to divert bile from the duodenum and to decompress the biliary system in the event edema or resulting fibrosis causes narrowing of the intrapancreatic portion of the common duct.

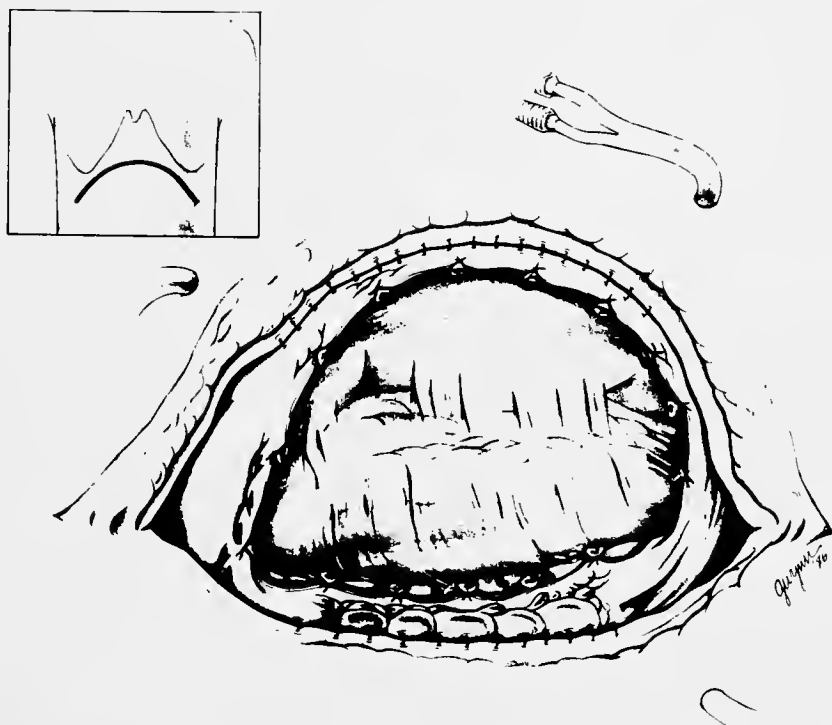


Figure 4. Location of abdominal incision and technique of exposure employed by the authors for "marsupialization" of the lesser sac.

A gastrostomy tube is placed since many of these patients require long-term gastric suction. A feeding jejunostomy is placed to allow postoperative alimentation. Because of the risk of intermittent bacteremia in these patients it is desirable to reduce the number of vascular cannulas. Sump drains are placed in the pancreatic bed to remove any fluid collection and for purposes of irrigation. They are usually removed in 48 hours to avoid erosion into adjacent structures.

To allow continued access in the postoperative period for daily débridement and irrigation of the pancreatic bed, the abdomen is left open. To prevent evisceration, the greater curvature of the stomach is sutured to the upper edge of the incision and the transverse colon is sutured to the lower edge. Portions of the omentum are used to obliterate the angles. If the preoperative diagnosis of necrotic pancreas is in error and only phlegmon is encountered, as was the case in ten of our patients, the same operation is performed except the abdomen is closed and no débridement is performed. Three of the 10 patients were dramatically improved following evacuation of amylase-rich brown cloudy fluid from the retrogastric space while the remaining seven gradually improved. In these it was less apparent that the operation was particularly beneficial; on the other hand, it was accomplished with no mortality.

In view of the 0% mortality and low morbidity when operating in error on pancreatic phlegmon, versus the disastrous outcome of non-operative therapy for necrotic and/or infected pancreas, we feel strongly that in situations where the diagnosis is in doubt, exploration should be strongly considered. All patients should receive at least one CT scan upon admission to the hospital, with 7-10 day follow-up as appropriate. High risk patients with more than four Ranson criteria positive, or patients whose condition is worsening, need frequent follow-up with scan so that prompt percutaneous or surgical intervention may be instituted. ■

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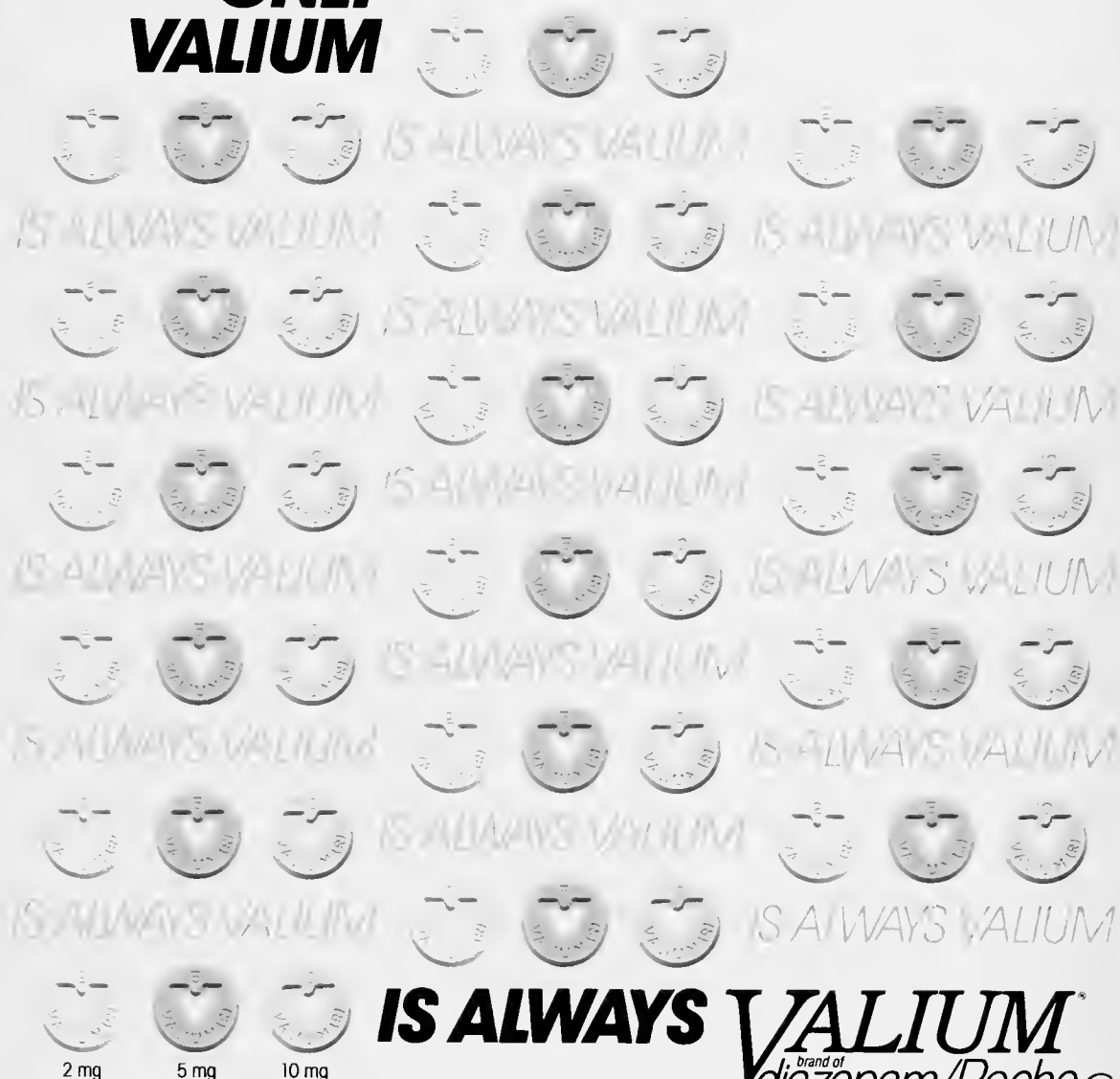
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Clinical Decision Making in a Cost Conscious Era

Cost Effective Evaluation of Clinical Decision Making

Andrew G. Wallace, M.D.

In the past the majority of clinical decisions were made by one doctor. The information underlying a decision was obtained from a few sources, the most expensive being examination by conventional x-ray. Today the doctor must choose among a number of expensive methods: routine x-rays, cineradiology, isotopic visualization, computer assisted tomographic scans and magnetic resonance imaging. There are multiple clinical approaches to a given diagnosis. At what point will new information be definitive enough to alter the clinical decision pattern that has been developed from the history, physical examination, chemical laboratory screen, chest plate and electrocardiogram, and be, as a consequence, cost effective? To be worth the expense, each additional test must supply enough new information to cause the doctor to vary from the course originally selected on the basis of tests previously performed. In this more complex environment three areas need to be examined.

1. How do we make rational clinical decisions and can we do it better?
2. How do we *maximize* the probability of favorable clinical outcomes for individual patients, yet at the lowest possible cost?
3. If we accept the premise that we are approaching limits on aggregate expenditure, then it is clear that the money spent for one purpose will not be available for another. At that point some issues will certainly become matters of public policy. It will be important to our patients that we contribute to those policies; the question is, how?

Clinical Decision Making¹⁻³

In 1978 Herb Simon was awarded the Nobel Prize in economics for pioneering research on how corporations make decisions. This work challenged the theory of organizational

behavior that was developed in the first half of this century — a theory which held that corporate decisions were made by a single omnipotent entrepreneur. He substituted a theory of multiple decision makers — a group — where choices were limited by uncertainty, biased by personal ties between decision makers, and influenced by ethical concerns. He portrayed corporate action as a compromise between points of view — designed to produce a satisfactory result, not necessarily the best — and focused on short-term or at best intermediate gain, rather than on distant goals.

The intriguing aspect of this story is that Simon's Nobel Prize was awarded in economics while his research was in cognitive psychology. More specifically, it was on how the central nervous system functions as an information processor. His papers provided the experimental basis for current understanding of pattern recognition. Well documented in his work are the remarkable differences between people's capacities for short- and long-term memory, and the observation that intellectual processes such as decision making operate on data stored in short-term memory — at least for the interval of time that decisions are made. It is to Simon and his colleagues that we owe much of the theory that underpins recent research on artificial intelligence.

We make decisions with the nervous system, and I submit that how the nervous system works, and what its limitations are, are relevant. Simon's work and ample subsequent evidence suggest that our brains are not built to hold simultaneously in short-term memory more than five to seven discrete facts for processing. As a consequence the system is not designed to sort through a large prior experience — to match one's current patient with those of similar description — and to compare benefits and risks resulting from one or more modes of therapy.

With many patients we probably collect more data than we can effectively use in decision making, and our capacity to recall a significant number of patients who are truly like the current patient is limited. At least in part these limitations of the nervous system have attracted many to computers, as an extension of our memory, to help identify prognostically significant variables, to perform pattern recognition,

From the Office of the Chief Executive Officer, Duke University Hospital, Durham 27710.

and to recall and codify the outcomes of one therapy versus another.

Sir William Osler, in his valedictory address to the University of Minnesota's class of 1892, wrote, "Start with the conviction that absolute truth is hard to reach about our fellow creatures — healthy or not — that slips in observation are inevitable, and that errors of judgement must occur in the practice of an art which consists largely of balancing probabilities. . . ."

We can trace at least to Osler that physicians deal most of the time with observations and test results that are prone to error, and with uncertainty about prognosis. As a consequence, we have always used probabilities, either consciously or unconsciously.

When the choice was between one diagnostic test and none, or between the only treatment and none, probabilities sorted themselves into reasonably distinct categories and could be handled without much precision or complex algorithms.

But for us the situation is more complicated. For one thing, we simply have many more alternatives from which to choose. For another, many diagnostic tests are not definitive and their information contents overlap. In practice, the utility of most tests is not so much a question of their predictive accuracy, viewed in isolation, but rather the extent to which a given result changes the likelihood of a disease from its pretest probability. Many of these comments are equally germane to therapy; there are risks that must be considered and sometimes new problems are introduced by therapy.

It seems to me that the ultimate compliment to the medical profession is that complexity and uncertainty are dealt with and that most problems are solved appropriately. However, there is a basis for thinking we can do better and perhaps at lower cost.

Decision Analysis⁴⁻¹¹

Shortly after World War II, the need to make complex decisions and the availability of methods to aid the process gave birth to a new discipline called *decision analysis*. Initially used in such seemingly disparate fields as military strategic planning and game theory, this new discipline represented a marriage of cognitive psychology, data processing, statistics and artificial intelligence. Business embraced this new approach, and nearly every respected MBA program in our country now provides a heavy dose of decision analysis in its curriculum.

In 1959 a paper was published in *Science*, "Reasoning Foundations for Medical Diagnosis," the first I think to focus on the use of symbolic logic, probabilities and utility theory to understand medical decisions.

Just a year later, Homer Warner presented an address to the American Heart Association titled "A Mathematical Approach to Medical Diagnosis: Application to Congenital Heart Disease." Warner was the one to introduce cardiology

to decision sciences. His most recently published paper is titled, "Physician Oriented Applications of Artificial Intelligence."

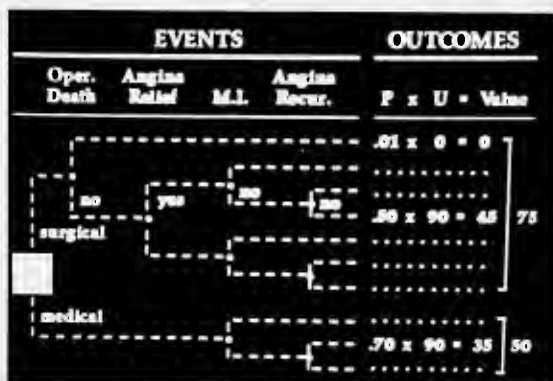


Figure 1

Figure 1 is a decision tree adapted from one published in the *Annals of Internal Medicine* a few years ago and dealing with choice about treating coronary disease. In principle, decision analysis is nothing more than an effort to formalize the process of making choices; and it is most useful when choices are complex and surrounded by uncertainty. Decision analysis asks its user (1) to be *explicit* in segmenting a complex problem into component events and possible actions, (2) to be *inclusive* by considering all potential outcomes, good and bad, (3) to be *quantitative* in the sense that probabilities should be specified for all important outcomes, and (4) to be *qualitative* by expressing on some scale the utility or preference for each outcome.

For each branch of a tree there is a solution or expected value, which is a product of the probability of that outcome and the utility associated with that outcome. Collectively, the solutions of a decision tree may be *prescriptive*, suggesting a choice that maximizes the probability of the desired outcome.

It is *not* my purpose to try to persuade you that decision analysis has reached a level of maturity that would make it practical in the everyday clinical setting; it has *not*. But this should not detract from the intrinsic value of subjecting decision making to critical analysis, or from our continuing responsibility to capture experience in a form suitable for *decision analysis*.

Consider for a moment the resources (human and fiscal) devoted over the last decade or two to outcome-oriented clinical cardiovascular research. For example: studies to determine the predictive accuracy of non-invasive tests; the appropriate timing of surgical intervention in congenital heart disease; the benefits and risks of one prosthetic heart valve versus another; the choice between medical and surgical therapy for subgroups of patients with coronary disease; the question of whether to pace or not in patients with repeated syncope; and the related questions of what constitutes an

Continued on page 221



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CORTISPORIN[®] OTIC Suspension Sterile (Polymyxin B-Neomycin-Hydrocortisone) Description: Each cc contains: Aerosporin[®] (Polymyxin B Sulfate) 10,000 units; Neomycin sulfate (equivalent to 3.5 mg neomycin base); 5 mg Hydrocortisone 10 mg (1%). The vehicle contains the inactive ingredients: cetyl alcohol, propylene glycol, polysorbate 80, water for injection and thimerosal (preservative) 0.01%. **Indications:** For the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of the antibiotics and for the treatment of infections of mastoidectomy and fenestration cavities caused by organisms susceptible to the antibiotics. **Precautions:** This drug should be used with care in cases of perforated eardrum and in long-standing cases of chronic otitis media because of the possibility of ototoxicity caused by neomycin. **CORTISPORIN[®] OTIC Solution Sterile (Polymyxin B-Neomycin-Hydrocortisone)** Description: Each cc contains: Aerosporin[®] (Polymyxin B Sulfate) 10,000 units; Neomycin sulfate (equivalent to 3.5 mg neomycin base); 5 mg Hydrocortisone 10 mg (1%). The vehicle contains the inactive ingredients: cupric sulfate, glycerin, hydrochloric acid, propylene glycol, water for injection and potassium metabisulfite (preservative) 0.1%. **Indications:** For the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of the antibiotics. **Warning:** Contains potassium metabisulfite, a sulfite that may cause allergic type reactions (e.g., hives, itching, wheezing, anaphylaxis) in certain susceptible persons. Although the overall prevalence of sulfite sensitivity in the general population is probably low, it is seen more frequently in asthmatics or in atopic nonasthmatic persons. **Precautions:** This drug should be used with care when the integrity of the tympanic membrane is in question because of the possibility of ototoxicity caused by neomycin. **Adverse Reactions:** Stinging and burning have been reported when this drug has gained access to the middle ear. **Contraindications, Warnings, Precautions and Adverse**

Reactions Common to Both Products: Contraindications: These products are contraindicated in those individuals who have shown hypersensitivity to any of the components, and in herpes simplex, vaccinia and varicella. **Warnings:** As with other antibiotic preparations, prolonged treatment may result in overgrowth of nonsusceptible organisms and fungi. If the infection is not improved after one week, cultures and susceptibility tests should be repeated to verify the identity of the organism and to determine whether therapy should be changed. When using neomycin-containing products to control secondary infection in the chronic dermatoses such as chronic otitis externa, it should be borne in mind that the skin in these conditions is more liable than is normal skin to become sensitized to many substances, including neomycin. The manifestation of sensitization to neomycin is usually a low grade reddening with swelling, dry scaling and itching; it may be manifest simply as a failure to heal. During long term use of neomycin-containing products, periodic examination for such signs is advisable and the patient should be told to discontinue the product if they are observed. These symptoms regress quickly on withdrawing the medication. Neomycin-containing applications should be avoided for that patient thereafter. **Precautions:** If sensitization or irritation occurs, medication should be discontinued promptly. Patients who prefer to warm the medication before using should be cautioned against heating the solution above body temperature, in order to avoid loss of potency. Treatment should not be continued for longer than ten days. Allergic cross-reactions may occur which could prevent the use of any or all the following antibiotics for the treatment of future infections: kanamycin, paromomycin, streptomycin, and possibly gentamicin. **Adverse Reactions:** Neomycin is a not uncommon cutaneous sensitizer. There are articles in the current literature that indicate an increase in the prevalence of persons sensitive to neomycin.

*Caution: If perforation of the eardrum exists, specify Cortisporin Otic Suspension (this drug should be used with care in cases of perforated eardrum).

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adequate diagnostic evaluation, and what to do in the absence of diagnostic certainty.

The most important thing to remember is the complexity of decisions we make and the degree of uncertainty that prevails about an outcome when a series of complex decisions are linked together. We are fortunate that cardiology has made a commitment to quantify the accuracy of observations and to document the outcome of therapeutic decisions. Recently published studies dealing with coronary bypass surgery and with the evaluation of patients with syncope graphically illustrate the potential of decision analysis: to integrate what we have learned, to deal objectively with uncertainty, to estimate the utility of particular choices, and to consider the variability of patients' preferences when important outcomes are at stake.

Cost¹²

We are also concerned with the issue of cost. A few years ago I made a transition: relinquishing the post as Chief of Cardiology at Duke to assume responsibilities as chief executive officer of the hospital. As a cardiologist I took great pride in a compulsive evaluation of my patients, and I tried to instill that philosophy in our trainees. The patient with angina typically got a treadmill, nuclear scans and catheterization. The patient with a history of arrhythmia got an exercise test, Holter monitor, an electrophysiologic study and sometimes more. It was satisfying to dictate a discharge summary with "all the data," and in a vague way I felt that this approach was good for the hospital and for the department in financial terms.

But the approach I espoused was being challenged. For example, results of treadmill testing and nuclear scans added little prognostic information for the patient with typical angina who would be catheterized anyway. Conversely, the angiogram seldom changed therapeutic strategies in patients with atypical pain, good exercise tolerance and negative scans. Electrophysiologists clarified the cause of syncope in only a third or fewer of the patients with non-diagnostic ECGs and ambulatory recordings.

With the introduction of fixed reimbursement by Medicaid and by Medicare, we all have had to deal with major institutional consequences of work-ups where there is a consistent pattern of cost in excess of prospectively set reimbursement. How do we decide if the expected value of a test justifies its cost?

Even without considering cost, I think we can agree that (as suggested by figure 2) for any diagnostic test to be of value it should satisfy at least two criteria: the test should convey incremental information that changes the pretest probability of disease or clarifies its severity; and the degree of change in probability should be sufficient to affect some subsequent decision.

It is important to recall here that decision analysis is more than just statistics; it embraces another set of consid-

Cost Conscious Decisions

- Incremental Information
(redundancy)
- Expected Value-Utility
(degree of change)
- Cost and Reimbursement
(alternatives)

Overall Benefit : Cost

Figure 2

erations which in the jargon of the discipline is called utility theory. It is here that all possible outcomes good and bad are considered, and their relative values are integrated to answer the question: what is the expected value of the test or treatment? When overall benefit is quantified it can be compared to cost — or to reimbursement — and ratios of benefit to cost for various alternatives can be compared.

Let me paraphrase the question I posed earlier: can we improve on the intuitive process of making decisions to maximize the probability of preferred outcomes while at the same time reducing cost? I believe the answer is yes. I am *not* an advocate of replacing with computers the remarkable capacity of experienced physicians to make judgments. But the complexity of some decisions, the availability of objective data from a host of relevant experiences, the ability to update these experiences over time and to apply the techniques of decision science, offer real promise of augmenting what in the end will always be clinical judgment.

In addition, the potential to reduce cost is real because nearly every line of evidence — intuitive and analytic — suggests that significant dollars are being spent collecting data that don't really help make therapeutic decisions, and for some patients very large amounts of money are spent on therapy that doesn't really alter the outcome of end stage disease.

Cost Effective Evaluation^{13, 14}

To this point, I have focused on how physicians make decisions regarding individual patients, optimizing outcomes and attempting where possible to eliminate unnecessary tests in the interest of reducing cost. The definition of cost effectiveness (Figure 3, next page) introduces something new: *a given level of resources* implies "a limit," and *aggregate health benefit* implies that decisions on how to use those resources will be guided by what is in the best interest of a group or population.

The national debt, predicted bankruptcy of the Medicare Trust Fund, and the speed with which corporate groups are opting for pre-paid health maintenance organizations are

Cost Effective Evaluation

**For any given level of resources,
which decisions will maximize the
aggregate health benefit for the
population of concern?**

Net Cost : Expected Benefit : Society

Figure 3

ample evidence that in the minds of many, resources available to spend on health are approaching a limit. If and when limits are reached, questions about how these dollars will be spent will become a matter of public policy.

The policy makers are already turning to analysts and to decision science for advice. I serve on the board of the Center for Health Policy at Duke, and new requests for analyses appear monthly, to assess this technology or that, the artificial heart, TPA, screening for glaucoma, cancer control, mental health, to name just a few.

The bottom line of these requests is cost effectiveness — the ratio of total net cost to expected benefit for a population: dollars spent for each month or year of quality adjusted increase in life expectancy. Suppose for example that the American Heart Association had a billion dollars and only a billion, with which to fund programs each year. Further, suppose that the choices offered for funding were an artificial heart program, a detection and treatment program for hypertension, and an anti-smoking program. Suppose further that with a billion dollars to spend every year, one of these programs would increase average life expectancy by one week, another by one year and another by two years for every American who reached his or her 25th birthday. Which would you vote for? Which is in the best interest of today's healthy population and of future generations?

These kinds of questions are being asked in the context of public policy and with the threat of limits on aggregate expenditure. What should be our position as individual physicians and as members of the AHA?

Cardiology has an enormous opportunity and responsibility to help answer these questions. How do we do it?

We can start by accepting even more broadly than we already have that the evaluation and treatment of every patient is a clinical experiment; that it is important to document baseline characteristics, the results of diagnostic tests, and the outcome of treatment, good or bad.

We can participate more fully and more willingly in clinical trials and registries that address important clinical problems.

We can encourage our students to become informed about

decision analysis as a strategy for augmenting their own clinical judgment as well as an opportunity to shape important policies that seem certain to influence their practice.

Finally, we have a choice in how we respond to the cost conscious era of clinical decision making. We can view it as a threat or even as an onerous breach of our social contract with patients, or we can use it as a stimulus to improve our teaching, to cultivate clinical judgment, to avoid unnecessary testing, to counter defensive medicine and to re-establish public trust that what we do is right and prudent. If we save money in the process, that will be a dividend, but even if we don't we will be positioned to clarify better than we can now the consequences and trade-offs of policy that limits health care expenditures. ■

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Before prescribing, see complete prescribing information in SK&F CO. literature or PDR. The following is a brief summary.

*** WARNING**

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K⁺ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K⁺ intake. Associated widened QRS complex or arrhythmia requires prompt additional therapy. Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: The bioavailability of the hydrochlorothiazide component of 'Dyazide' is about 50% of the bioavailability of the single entity. Theoretically, a patient transferred from the single entities of triamterene and hydrochlorothiazide may show an increase in blood pressure or fluid retention. Similarly, it is also possible that the lesser hydrochlorothiazide bioavailability could lead to increased serum potassium levels. However, extensive clinical experience with 'Dyazide' suggests that these conditions have not been commonly observed in clinical practice. Angiotensin-converting enzyme (ACE) inhibitors can elevate serum potassium; use with caution with 'Dyazide'. Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids). (ACE) Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function. Thiazides may add to or potentiate the action of other antihypertensive drugs. Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth; anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions; nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics); necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

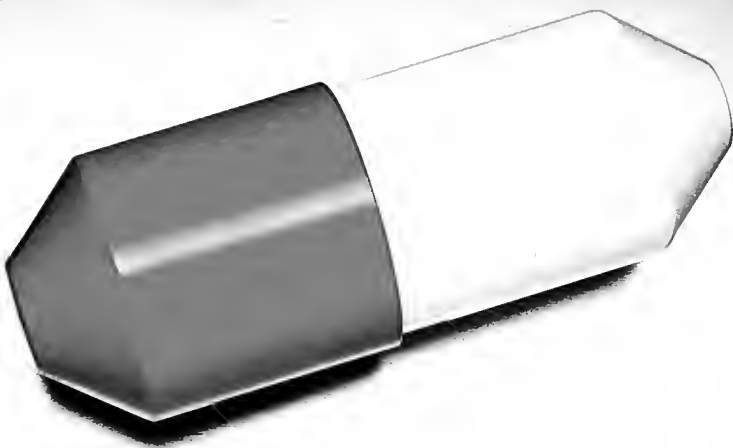
Supplied: 'Dyazide' is supplied as a red and white capsule, in bottles of 1000 capsules; Single Unit Packages (unit-of-use) of 100 (intended for institutional use only); in Patient-Pak™ unit-of-use bottles of 100.

BRS-DZ L42

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Serum K⁺ and BUN should be checked periodically (see Warnings and Precautions).



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TIMING IS KEY



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EVERYTHING

Effective control time and time again¹

Effective control of fasting and postprandial glucose—patient after patient, meal after meal, year after year.

Insulin when it's needed

Insulin levels are rapidly elevated in response to a meal, then return promptly to basal levels after the meal challenge subsides.

Timed to minimize risks

Rapidly metabolized and excreted, with an excellent safety profile.¹ As with all sulfonylureas, hypoglycemia may occur.

In concert with diet in non-insulin-dependent diabetes mellitus

Glucotrol[®]

(glipizide) 5-mg and 10-mg
Scored Tablets



SYNCHRONIZED SULFONYLUREA THERAPY



Please see brief summary of Glucotrol[®] (glipizide) prescribing information on next page.

ROERIG 
A Division of Pfizer Inc., New York, NY 10017

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GLUCOTROL® (glipizide) Tablets

Brief Summary of Prescribing Information

INDICATIONS AND USAGE: GLUCOTROL is indicated as an adjunct to diet for the control of hyperglycemia in patients with non-insulin-dependent diabetes mellitus (NIDDM, type II) after an adequate trial of dietary therapy has proved unsatisfactory.

CONTRAINDICATIONS: GLUCOTROL is contraindicated in patients with known hypersensitivity to the drug or with diabetic ketoacidosis, with or without coma, which should be treated with insulin.

SPECIAL WARNING ON INCREASED RISK OF CARDIOVASCULAR MORTALITY: The administration of oral hypoglycemic drugs has been reported to be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin. This warning is based on the study conducted by the University Group Diabetes Program (UGDP), a long-term prospective clinical trial designed to evaluate the effectiveness of glucose-lowering drugs in preventing or delaying vascular complications in patients with non-insulin-dependent diabetes. The study involved 823 patients who were randomly assigned to one of four treatment groups (Diabetes, 19, supp. 2:747-830, 1970).

UGDP reported that patients treated for 5 to 6 years with diet plus a fixed dose of tolbutamide (1.5 grams per day) had a rate of cardiovascular mortality approximately 2-1/2 times that of patients treated with diet alone. A significant increase in total mortality was not observed, but the use of tolbutamide was discontinued based on the increase in cardiovascular mortality, thus limiting the opportunity for the study to show an increase in overall mortality. Despite controversy regarding the interpretation of these results, the findings of the UGDP study provide an adequate basis for this warning. The patient should be informed of the potential risks and advantages of GLUCOTROL and of alternative modes of therapy.

Although only one drug in the sulfonylurea class (tolbutamide) was included in this study, it is prudent from a safety standpoint to consider that this warning may also apply to other oral hypoglycemic drugs in this class, in view of their close similarities in mode of action and chemical structure.

PRECAUTIONS: Renal and hepatic disease: The metabolism and excretion of GLUCOTROL may be slowed in patients with impaired renal and/or hepatic function. Hypoglycemia may be prolonged in such patients should it occur.

Hypoglycemia: All sulfonylureas are capable of producing severe hypoglycemia. Proper patient selection, dosage, and instructions are important to avoid hypoglycemia. Renal or hepatic insufficiency may increase the risk of hypoglycemic reactions. Elderly debilitated or malnourished patients and those with adrenal or pituitary insufficiency are particularly susceptible to the hypoglycemic action of glucose-lowering drugs. Hypoglycemia may be difficult to recognize in the elderly or people taking beta-adrenergic blocking drugs. Hypoglycemia is more likely to occur when caloric intake is deficient, after severe or prolonged exercise, when alcohol is ingested, or when more than one glucose-lowering drug is used.

Loss of Control of Blood Glucose: A loss of control may occur in diabetic patients exposed to stress such as fever, trauma, infection or surgery. It may then be necessary to discontinue GLUCOTROL and administer insulin.

Laboratory Tests: Blood and urine glucose should be monitored periodically. Measurement of glycosylated hemoglobin may be useful.

Information for Patients: Patients should be informed of the potential risks and advantages of GLUCOTROL, of alternative modes of therapy, as well as the importance of adhering to dietary instructions, of a regular exercise program, and of regular testing of urine and/or blood glucose. The risks of hypoglycemia, its symptoms and treatment, and conditions that predispose to its development should be explained to patients and responsible family members. Primary and secondary failure should also be explained.

Drug Interactions: The hypoglycemic action of sulfonylureas may be potentiated by certain drugs including non-steroidal anti-inflammatory agents and other drugs that are highly protein bound, salicylates, sulfonamides, chloramphenicol, probenecid, coumarins, monoamine oxidase inhibitors, and beta adrenergic blocking agents. *In vitro* studies indicate that GLUCOTROL binds differently than tolbutamide and does not interact with salicylate or dicumarol. However, caution must be exercised in extrapolating these findings to a clinical situation. Certain drugs tend to produce hyperglycemia and may lead to loss of control, including the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid. A potential interaction between oral miconazole and oral hypoglycemic agents leading to severe hypoglycemia has been reported. Whether this interaction also occurs with the intravenous topical or vaginal preparations of miconazole is not known.

Contraception, Multiparity, Impairment of Fertility: A 20-month study in rats and an 18-month study in mice at doses up to 75 times the maximum human dose revealed no evidence of drug-related carcinogenicity. Bacterial and *in vivo* mutagenicity tests were uniformly negative. Studies in rats of both sexes at doses up to 75 times the human dose showed no effects on fertility.

Pregnancy: Pregnancy Category C: GLUCOTROL (glipizide) was found to be mildly fetotoxic in rat reproductive studies at all dose levels (5-50 mg/kg). This fetotoxicity has been similarly noted with other sulfonylureas, such as tolbutamide and tolazamide. The effect is perinatal and believed to be directly related to the pharmacologic (hypoglycemic) action of GLUCOTROL. In studies in rats and rabbits no teratogenic effects were found. There are no adequate and well-controlled studies in pregnant women. GLUCOTROL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Because recent information suggests that abnormal blood glucose levels during pregnancy are associated with a higher incidence of congenital abnormalities, many experts recommend that insulin be used during pregnancy to maintain blood glucose levels as close to normal as possible.

Nonteratogenic Effects: Prolonged severe hypoglycemia has been reported in neonates born to mothers who were receiving a sulfonylurea drug at the time of delivery. This has been reported more frequently with the use of agents with prolonged half-lives. GLUCOTROL should be discontinued at least one month before the expected delivery date.

Nursing Mothers: Since some sulfonylurea drugs are known to be excreted in human milk, insulin therapy should be considered if nursing is to be continued.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: In controlled studies, the frequency of serious adverse reactions reported was very low. Of 702 patients, 11.8% reported adverse reactions and in only 1.5% was GLUCOTROL discontinued.

Hypoglycemia: See PRECAUTIONS AND OVERDOSAGE sections.

Gastrointestinal: Gastrointestinal disturbances, the most common, were reported with the following approximate incidence: nausea and diarrhea, one in 70; constipation and gastritis, one in 100. They appear to be dose-related and may disappear on division or reduction of dosage. Cholestatic jaundice may occur rarely with sulfonylureas. GLUCOTROL should be discontinued if this occurs.

Dermatologic: Allergic skin reactions including erythema, morbilliform or maculopapular eruptions, urticaria, pruritus, and eczema have been reported in about one in 70 patients. These may be transient and may disappear despite continued use of GLUCOTROL. If skin reactions persist, the drug should be discontinued. Porphyrinuria, calcaemia, and photosensitivity reactions have been reported with sulfonylureas.

Hematologic: Leukopenia, agranulocytosis, thrombocytopenia, hemolytic anemia, aplastic anemia, and pancytopenia have been reported with sulfonylureas.

Metabolic: Hepatic porphyria and disulfiram-like alcohol reactions have been reported with sulfonylureas. Clinical experience to date has shown that GLUCOTROL has an extremely low incidence of disulfiram-like reactions.

Endocrine Reactions: Cases of hyponatremia and the syndrome of inappropriate antidiuretic hormone (SIADH) secretion have been reported with this and other sulfonylureas.

Miscellaneous: Dizziness, drowsiness, and headache have been reported in about one in fifty patients treated with GLUCOTROL. They are usually transient and seldom require discontinuance of therapy.

OVERDOSAGE: Overdosage of sulfonylureas including GLUCOTROL can produce hypoglycemia. If hypoglycemic coma is diagnosed or suspected, the patient should be given a rapid intravenous injection of concentrated (50%) glucose solution. This should be followed by a continuous infusion of a more dilute (10%) glucose solution at a rate that will maintain the blood glucose at a level above 100 mg/dL. Patients should be closely monitored for a minimum of 24 to 48 hours since hypoglycemia may recur after apparent clinical recovery. Clearance of GLUCOTROL from plasma would be prolonged in persons with liver disease. Because of the extensive protein binding of GLUCOTROL (glipizide), dialysis is unlikely to be of benefit.

DOSEAGE AND ADMINISTRATION: There is no fixed dosage regimen for the management of diabetes mellitus with GLUCOTROL. In general, it should be given approximately 30 minutes before a meal to achieve the greatest reduction in postprandial hyperglycemia.

Initial Dose: The recommended starting dose is 5 mg before breakfast. Geriatric patients or those with liver disease may be started on 2.5 mg. Dosage adjustments should ordinarily be in increments of 2.5-5 mg, as determined by blood glucose response. At least several days should elapse between titration steps.

Maximum Dose: The maximum recommended total daily dose is 40 mg.

Maintenance: Some patients may be effectively controlled on a once-a-day regimen, while others show better response with divided dosing. Total daily doses above 15 mg should ordinarily be divided.

HOW SUPPLIED: GLUCOTROL is available as white, dye-free, scored diamond-shaped tablets imprinted as follows: 5 mg tablet—Pfizer 411 (NDC 5 mg 0049-4110-66) Bottles of 100, 100 mg tablet—Pfizer 412 (NDC 10 mg 0049-4120-65) Bottles of 100.

CAUTION: Federal law prohibits dispensing without prescription.

More detailed professional information available on request.

ROERIG



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IF YOU HAD
MY JOB."



YOU COULD LEARN A LOT
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A Public Service Message Ad U.S. Department of Transportation

When Your Patient Decides To Die

Robert J. Sullivan, Jr., M.D.

The conference topic was the patient's right to refuse life-sustaining treatment. As I sat listening to the guest lecturer, my thoughts turned to a patient I had cared for several years earlier.

Mrs. M. had had a wonderful life. Born early in the century, she was a graduate of a top university and enjoyed a successful career in publicity and marketing. She had been married twice. She had no children and all of her family were now gone.

Her health had been superb until vaginal bleeding led to a diagnosis of uterine cancer. Subsequent surgery revealed widespread metastasis. She received radiation therapy twice for recurrences. The first bowel obstruction was one year later and resolved spontaneously. A second obstruction led to surgery where diffuse severe radiation fibrosis was discovered. Fortunately, all evidence pointed to cure of the cancer. Three months later, she obstructed again. It was then that she took matters firmly in her own hands.

First she refused any diagnostic tests. Then she decided to discontinue intravenous fluids. The medical staff was abruptly diverted from its accustomed headlong pursuit of medical cure by her obstinate refusal to permit intervention. She said she had accepted the initial cancer surgery, radiation therapy and surgical relief of obstruction on the assumption that she would have a normal life thereafter. Now, faced with a probable colostomy and likely future obstructive episodes, she was disenchanted with our ability to effect a cure and her intention was therefore to cease further treatment. Life for her was not worth living if she could not deport herself in an independent and active way. Since we could not return her to her original condition, death was her choice. She asked me to administer morphine intravenously and end it all.

I was appalled. She said I had a choice of how she was going to die; slowly and painfully, or quickly. But she was going to die.

Numerous consultations followed with surgeons, internists, psychiatrists, psychologists, nurses, nurse practitioners, social workers, clergy, trust officers, administrators, and attorneys. Several conclusions emerged from hours of discussions.

1 She was in her right mind. She was not depressed, demented or psychotic. Her entire life reflected a pattern of decision and determination.

2 She knew the consequences of surgery and of refusing surgery.

3 She never waived in her story of why she accepted her past therapy and why she was refusing future therapy.

4 There were no family members alive who could help us or her with this decision.

5 No surgeon would operate on a competent and well-informed woman who refused to sign a surgical permission and threatened to sue if any procedure were done.

6 I could do nothing myself to save her without surgery.

7 She would soon die if she persisted in her refusal to accept therapy.

She was soon transferred from the medical center to my care at a nursing home. I visited her daily and together we faced the implementation of her decision. I told her I could never assist in terminating her life. She told me she would only accept treatment that lead to comfort and nothing that would prolong her life. Accordingly, we agreed on a gastric suction tube to eliminate vomiting and a urine catheter to eliminate the need for a bed pan (she found it degrading) or trips to the bathroom (she was too weak). I agreed to administer morphine injections every four hours to relieve pain in her abdomen presumably due to obstruction and/or ischemic bowel. And that was it. She accepted ice chips to keep her mouth moist but refused even hard candy in fear that it would provide sustenance. I told her it would be a week at the most and all would be over. Her trust officer arranged a final copy of her will. Then she settled back to write everyone she knew a last letter.

I was in a quandary. I could not condone suicide, and her death from a potentially curable obstruction seemed close to it. Yet her logic was good and her right to make this decision seemed clear. I returned to Hippocratic principles and first did no harm: I refused to administer morphine beyond that necessary for pain relief. Then I did everything possible to relieve suffering.

It didn't take a week for her to die. It took more than four weeks. She had considerable ascites and edema fluid accumulated which sustained her circulation and renal function beyond my wildest estimates. Despite continuous nasogastric suction and the absence of oral or intravenous

From Duke University Medical Center, Department of Medicine, Durham 27710.

intake, she persisted lucid and alert. I began to feel I was indeed torturing this elegant and determined woman who came to resemble a famine or war-camp victim. She never wavered in her resolve to die and she never let me forget the problems I was causing by my refusal to end her life for her. I had numerous conversations about her with my colleagues but still the burden was mine and I felt it deeply. We were both unburdened when she died on day 29 after her decision.

The conference speaker concluded with a review of recent court cases that acknowledge rights of patients to refuse life-

sustaining treatment. I took some comfort in the fact that others were confused on precisely the same issues I had faced in caring for Mrs. M. Things were far from clear, as shown by the numerous suits, counter suits, and conflicting ethical and legal opinions.

I left the meeting with the same doubt and uncertainty I had felt years before when Mrs. M. put me to the test. I still admire her courage and fortitude. She knew how to live. And when life was over for her, she saw it clearly and insisted we let her go her own way. How awful. How wonderful. How rare. ■

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Letters to the Editor

To the Editor:

Thank you to you and your reviewer for your thoughtful criticisms of my paper on exercise and longevity. After careful consideration, I believe many of the criticisms were valid. The original objective of the paper was to comply with my epidemiology course assignment to perform an extensive analysis of only three or four manually selected, representative articles on a topic of interest. I still contend that this objective was accomplished. However, I can now clearly see that the Journal's readers would be better served by a more extensive, systematic and computerized literature search with a more comprehensive perspective of all the available evidence.

Although the paper was rejected, I enjoyed writing it, earned a perfect grade and learned a great deal from your criticisms — for which I will always be grateful. Some day, I will submit a different and better article to your Journal for publication. With the experience gained on this first attempt, I will succeed!

Thomas Funcic
237 D Jackson Circle
Chapel Hill 27514

Reply to Dr. Mack's paper

To the Editor:

I read with great interest the article by Ronald B. Mack, M.D., in the *North Carolina Medical Journal*, on hydrogen sulfide poisoning (World Enough and Time — Hydrogen Sulfide Poisoning, 1986;47:33-4).

I believe further clarification as to the physiology of the colored halos is appropriate. The effects of hydrogen sulfide on the eyes most commonly occur at concentrations so low that they have no systemic effect. The ocular symptoms generally start after several hours of exposure, and may not appear until the patient had finished the work for the day. The workmen may also be exposed to low concentrations of the hydrogen sulfide gas and become accustomed to the initial unpleasant odor. This adaptation to the unpleasant odor provides them the environment for continued ocular injury. The corneal epithelial surface develops a fine punctate stain visible by split lamp biomicroscopy. The corneal epithelial injury results in a vesicle formation in the basal epithelial layer. This acts as a diffraction grating.

The refractive index of the edema fluid is different from the surrounding epithelial cells. When this difference in the index of refraction has a regular pattern it will serve as a diffraction grating and will be responsible for the appearance of the rainbow colored halos. The accumulation of fluid in the cornea is also the reason patients experiencing an acute attack of glaucoma also have colored halos around lights.

I made this article available to my wife who works as a

chemist in a municipal waste treatment plant. She made the article available to her co-workers who are exposed to the potential of hydrogen sulfide poisoning. Their primary comment was, "Hydrogen sulfide can kill." The article treats it more as a joke. That was my impression as I read this otherwise informative article.

It is unfortunate that the serious tone of the article was distracted by the multiple attempts at humor.

I have found the new format of the *North Carolina Medical Journal* enjoyable and very useful to both my own professional needs, as well as the interest of my friends and patients. Dr. Mack's feature articles on toxic encounters have been especially interesting to me and I hope to continue to be able to read them in future articles.

Joseph Majstoravich, Jr., M.D.
P.O. Box 1317
18 Medical Park
Morehead City 28557-1317

Response from Dr. Mack:

I wish to extend my thanks to Dr. Joseph Majstoravich, Jr. for his clarification of the pathophysiology of colored halos as reported by some patients with hydrogen sulfide poisoning. I am certainly grateful for his willingness to share his knowledge.

As far as the treatment of this poisoning as a "joke" as Dr. Majstoravich has concluded after reading my article, I must take umbrage. Quite to the contrary I tried to stress, in several places in the article, that hydrogen sulfide kills and that time is the essence vis-a-vis diagnosis and emergency treatment.

It is my opinion that humor is a trait in man (and woman, I hope) that has been selected out to help survival of our species. Certainly the use of humor in medicine can be useful in assuaging anxiety in such stressful situations as an article on poisoning, in helping readers to remember the salient features of the written words and to allow the author to express to his readership that life in general and the practice of medicine is so serious that it should never be taken seriously. There are many physicians in this state who can write informative articles on toxicology; my meager talent, if it exists, is to present the material to non-toxicology-minded physicians who want to add to their data base in a relatively painless manner. Far from taking away from our humanity, I believe humor expresses it.

Ronald B. Mack, M.D.
Associate Professor of Pediatrics
Wake Forest University
Bowman Gray School of Medicine
300 S. Hawthorne Rd.
Winston-Salem 27103

Replies to Professor Hauerwas's editorial

To the Editor:

In his reply (NCMJ 1987;48:67-8) to the editorial "Sobering Thoughts" by Crist et al (1986;47:511) and subsequent letters, Professor S. Hauerwas discussed both the diversity of Catholicism and abortion. He did not define or discuss "overpopulation." By ignoring overpopulation, the discussion on abortion was like a discourse on fish without mentioning that they live in water.

Let me define "overpopulation." A country is overpopulated when its rate of utilization of resources significantly exceeds a possible steady state. Since we have a large trade deficit and are daily importing more than a million barrels of oil, the USA already is a seriously overpopulated country.

Professor Hauerwas eloquently presents the diversity of Catholicism. Of course, some differences are allowed in the Catholic Church. But a contrary case also can be made. Low level clergy who do not ardently support the Vatican's policies seldom become Cardinals. Furthermore, Catholic theology professors who do not follow the Vatican's teachings on prohibiting contraceptives can be stripped of their teaching privileges.

Where society at large must support the offspring, the Catholic Church has policies which favor large families. Where the Catholic church itself would be responsible for the care, such as the possible offspring of priests and nuns, it requires strict celibacy and chastity. The policy apparently reverses 180° according to who will be bearing the expense.

Where we differ is that Professor Hauerwas apparently does not consider overpopulation to be a serious problem in the USA. I think overpopulation is a major problem; and, unless we soon do something effective about controlling the growth of population, we shall almost surely lose our democracy and many freedoms we now cherish.

In an old story, ostriches sometimes hide their heads in the sand to avoid seeing danger. The story unfortunately has the wrong animal. It is we humans, not ostriches, who often do not wish to see impending trouble.

Albert D. Warshawer, M.D.
1608 East Fifth Street
Greenville 27858

To the Editor:

This is in response to the editorials by Dr. Crist and his colleagues and Dr. Hauerwas. The abortion and religious controversies aside, it is true that American women have fewer contraceptive methods available than women in other countries. Two methods not available to U.S. women in 1987 are the injectable contraceptive depot medroxyprogesterone acetate (Depo Provera, Upjohn) and the intrauterine device (IUD). Although Depo Provera is now available in 84 countries around the world, the Food and Drug Administration (FDA) has not approved it for contraceptive indications (it is available for other indications). The FDA Commissioner went against the recommendation of his advisory board when he decided to withhold approval.

The case of IUDs is a little different, as they continue to enjoy the approval of the FDA. The IUD is no longer marketed because of the American propensity to bring product liability suits for anything less than perfection. The reputation of the IUD as a contraceptive method has suffered greatly as a result of the Dalkon Shield — an IUD with serious defects from which the FDA *did* withdraw its approval. What the accumulated epidemiologic evidence on IUDs tells us is that IUDs should be prescribed only to a limited group of women, those at low risk of contracting sexually transmitted disease. For this limited group the IUD remains an excellent method of contraception — if available. Physicians and epidemiologists understand that pelvic inflammatory disease and subsequent infertility are caused by sexually transmitted diseases which IUDs, unlike some other contraceptive methods, do nothing to prevent. Juries, unfortunately, rarely understand this.

A similar fate may befall spermicidal products. A federal appellate court recently upheld the award of \$4.8 million to the parents of a congenitally malformed child conceived during spermicide jelly use. The original trial judge and the appeals decision rejected the weight of epidemiologic evidence that spermicides do not cause malformations. In fact, the FDA had previously ruled that spermicidal products need not include warnings of birth defects on their labels. The appellate decision stated that "product liability law does not preclude recovery until a 'statistically significant' number of people have been injured. . . ." But injured by what? Spermicides have been termed the newest "litogen" — a drug that does not cause malformations but does cause lawsuits.

No method of contraception is perfect; even condoms can cause latex irritation. Are we to lose all these methods because somebody sues? Will the epidemic of unintended pregnancies worsen in light of reduced family planning choices? Most people don't remember the days when rhythm, condoms and illegal abortion were the only choices, but we may be headed in that direction unless we can put things in a clearer perspective.

Judith A. Fortney, PhD
Paul J. Feldblum, MSPH
Reproductive Epidemiology Division
Family Health International
Research Triangle Park, NC 27709

To the Editor:

I have just read the editorial "Catholicism and Ethics" by Stanley Hauerwas, Ph.D. Thank you.

David Ames, M.D.
313 Longmeadow Rd.
Greenville, 27858

Concerns about Dr. Dykers's project

To Dr. John R. Dykers, Jr.:

We certainly appreciate your interest in the recognition and control of sexually transmitted diseases. However, we

have a number of concerns about the SAFECARD [AIDCARD] project you describe. Thank you for the opportunity to comment.

Taking each test in turn: HTLV-III or HIV antibody testing may appropriately be used to assist in diagnosis for individuals with signs and symptoms suggestive of HIV infection. However, its usefulness as a screening test is much less well established at the present time. First of all, recommendations for preventing acquisition and transmission of HIV are essentially identical:

- 1 limit number of sex partners (lifetime monogamy is safest);
- 2 if an individual or his/her partner has had more than one partner, avoid exchange of blood, semen, and vaginal fluids during sex (condoms are one way to do this);
- 3 don't use IV drugs, persons who do shouldn't share needles and should follow safer sex guidelines;
- 4 don't share other items which might be contaminated with blood, e.g. razors and toothbrushes.

These recommendations apply to everyone regardless of whether or not they belong to an AIDS high risk group, whether or not they have been tested, and whether or not they are antibody positive. We feel *strongly* that testing is an *adjunct* to careful risk-reduction counseling and that it has little merit apart from counseling. Test reliability and interpretation is of concern: will EIA results be repeated and confirmatory testing by Western Blot (WB) or IFA be done before they are reported? Will results be reported to individuals without proper interpretation by a health care professional about what they mean? Some negatives are falsely negative, particularly for recently infected individuals, and may lead to a false sense of security and to transmission of the virus to others unless proper risk reduction behaviors are followed. In low prevalence populations — such as heterosexuals who are not hemophiliacs, IV drug users, or sex partners of someone known to be at high risk — as many as 9 of every 10 positive EIA results are false positives. These are not entirely clarified by confirmatory testing by WB. The sensitivity of WB is unknown but appears to be much lower than EIA, hence some true positives will be negative by WB. As you can see, interpretation of HIV antibody test results is complex and difficult.

An additional concern is issuance of a SAFECARD [AIDCARD[®]]. This indicates a presumption that negative tests signify the absence of infection and risk associated with sexual contact. This cannot be defended on two grounds:

- 1 a negative test may be falsely negative as noted above;
- 2 the tested individual may become infected the day following testing because of a false sense of security and may transmit to others.

Public health officials in California succeeded in prohibiting this and similar systems several months ago on the grounds

that it threatened public health. We feel that the SAFECARD system represents a serious and grave threat to the public health. We must strongly discourage its implementation.

Regarding the other tests: As you mention chlamydia antibodies are poorly correlated with current infection. Their utilization as a screening tool for infection cannot be defended. Indeed their usefulness in diagnosis is limited, and only when a four-fold rise in titer is found on convalescent sera in symptomatic patients is diagnostic testing valid. Both HBsAg and RPR are useful diagnostic tests and appropriate screening tests in populations at increased risk. A few years ago the requirement for premarital syphilis serologies was removed from the law because the low prevalence fails to justify the cost of screening. In any case, marketing of these tests directly to the lay population has serious public health implications. By law, all positive syphilis serologies and cases of Hepatitis B and laboratory confirmed chlamydia must be reported to public health authorities. While the laboratory doing these tests would hopefully report positive RPR's, it is likely that many would be low titer biological false positives and others residual standing titers due to previously treated syphilis. Many individuals would misinterpret results as positive when they were clinically insignificant and negative when infection was present. Many in both groups would fail to seek medical care while others would attempt self-medication, and still others would suffer grave, unnecessary psychological and social consequences.

Diagnosis of each of these conditions should be done by well trained, competent health care providers. Physicians should certainly maintain a high index of suspicion for each of these conditions in their adolescent and adult patients, most of whom are sexually active and few, monogamous for life. Diagnostic and treatment services for hepatitis B, chlamydia, syphilis, and other sexually transmissible diseases are available free of charge at all local health departments where confidentiality is assured. Anonymous AIDS antibody testing and *counseling* are available at no charge in 95 of 100 local health departments in North Carolina. The staff in these health departments have received substantial training in pre- and post-test counseling and risk reduction education.

We feel strongly that the SAFECARD [AIDCARD[®]] program is a serious threat to the public health and should not be implemented. We believe that counseling, testing, and the provision of proper control measures (including treatment, contact notification as appropriate, and risk reduction education) absolutely must accompany all screening for communicable diseases.

J.N. MacCormack, M.D., M.P.H.

State Epidemiologist

R.A. Meriwether, M.D.

Head, Communicable Disease Control Branch
North Carolina Department of Human Resources

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IN STATE

April 9

North Carolina Clinical Neuro-Ophthalmology Review

Place: Chapel Hill

Info: Baird S. Grimson, M.D., Dept of Ophthalmology, University of North Carolina, 617 Clinical Science Bldg. 229H, Chapel Hill 27514. 919/966-5296

April 9-11

Advanced Vitreous Surgery Course V

Place: Chapel Hill

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

April 10

Plasma Cell Myeloma and Related Diseases

Place: Durham

Credit: 6 hours Category I AMA

Fee: \$75

Info: Myeloma Symposium, Box 3096 DUMC, Durham 27710

April 10-11

Advanced Cardiac Life Support Provider Course

Place: Asheville

Credit: 16 hours Category I AMA

Fee: \$200

Info: Daniel L. Dolan, M.D., MAHEC, 501 Biltmore Ave., Asheville 28801-4686. 704/258-0881

April 11

Indigent Health Care

Place: Asheville

Fee: \$5

Info: Carol Epps, NCMS, 800/722-1350; or Agnes Smith, NC Legal Services Resource Center, 919/821-0042

April 11-22

Highway Safety Conference

Place: Boone

Fee: \$25

Credit: 7 Hours Category I AMA

Info: W. Douglas Wooten, Head, Highway Safety Branch, Div. of Health Service, P.O. Box 2091, Raleigh 27602. 919/733-3222

April 22

Neonatal Emergencies: Recognition and Treatment

Place: Greenville

Credit: 6 hours Category I AMA

Fee: \$55

Info: Office of CME, ECU School of Medicine, P.O. Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

April 24-26

Second International DREZ Symposium (Dorsal Root Entry Zone)

Place: Research Triangle Park

Credit: 13 hours Category I AMA

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

April 25

Indigent Health Care

Place: Greenville

Fee: \$5

Info: Carol Epps, NCMS, 800/722-1350; or Agnes Smith, NC Legal Services Resource Center, 919/821-0042

April 25

Fifteenth Annual New Bern Symposium: The Care of the Elderly

Place: New Bern

Info: Wm. B. Hunt, Jr., M.D., Symposium Director, P.O. Box 2157, New Bern 28560. 919/633-8608

April 27-29

Doppler Echocardiography: Beginning with Color Flow Mapping

Place: Durham

Credit: 33 hours Category I AMA

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

April 27-May 1

Physical Aspects of Hyperthermia

Place: Durham

Credit: 33 hours Category I AMA

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

May 1-3

Women Physicians Meeting

Place: Asheboro

Credit: 5 hours AAFP

Info: Paula Baker, NCAFP. 919/781-6467

May 8-9

Emergencies of the Lung and Gut in Pediatric Patients

Place: Durham

Fee: \$90

Credit: 10 hours Category I AMA

Info: Dr. Alexander Spock, M.D., Duke University Medical Center, Box 2994, Durham 27710. 919/681-3364

May 9

Indigent Health Care

Place: Winston-Salem

Fee: \$5

Info: Carol Epps, NCMS, 800/722-1350; or Agnes Smith, NC Legal Services Resource Center, 919/821-0042

May 13

Common Diagnostic Problems in Surgical Pathology: A Practical Approach

Place: Greenville

Fee: \$55

Credit: 7 hours Category I AMA

Info: The Office of CME, ECU School of Medicine, P.O. Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

May 15

Adolescent Health Issues: The New Morbidities

Place: Durham

Credit: 8 hours Category I AMA

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

May 22

4th Annual Eye Conference — "Ocular Tumors"

Place: Winston-Salem

Info: Kirk Huske, Bowman Gray School of Medicine of Wake Forest University, Graylyn Conference Center, Winston-Salem 27103. 919/748-3971

June 3

Duke CME Series

Place: Durham

Credit: pending

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

June 5-7

Duke Eye Center Alumni Spring Meeting

Place: Chapel Hill

Credit: 8 hours Category I AMA

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

June 9

1987 Series — Duke Tuesday
Place: Durham
Credit: 5 hours Category 1 AMA
Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

June 11-13

34th Annual Mountaintop Medical Assembly
Place: Waynesville
Info: Mountaintop Medical Assembly, Waynesville 28786. 704/456-6021

June 15-17

Surgery for Coronary Artery Disease
Place: Durham
Fee: \$460 ACC members; \$525 others
Credit: 17 hours Category 1 ACCME
Info: Registration Secretary, Extramural Programs Dept., American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 800/253-4636; in MD or AK 301/897-5400

July 13-15

U.S. Olympic Festival Sports Medicine Conference: Part II, Athletic Injury Prevention and Treatment
Place: Durham
Credit: pending
Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

July 13-17

29th Annual Postgraduate Course/Morehead Symposium
Place: Durham
Credit: 26 hours Category 1 AMA; AAFP 24.75 prescribed
Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

July 27-31

10th Annual Radiology Postgraduate Course
Place: Atlantic Beach
Credit: 20 hours Category 1 AMA
Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

Nursing

Except where otherwise noted, contact Nettie Wilburn, CPS, Office of Continuing Education, University of North Carolina, Chapel Hill 27514. 919/966-3638

May 13-14

The Systematic Process of Instructional Development
Place: Chapel Hill
Credit: 13.2 CEUs pending
Fee: \$110

June 1-5

Preparation for NCLEX-RN
Place: Chapel Hill
Credit: 3.39 CEUs
Fee: \$75 UNC-CH students; \$85 others

June 1-19

Summer Institute: Gerontology for Nurse Educators
Place: Chapel Hill
Credit: 3 CEUs
Fee: \$3

OUT OF STATE

April 9-10

16th Annual School Health Education
Place: Johnson City, TN
Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

April 9-11

Thoracic Imaging Update
Place: Monterey, CA
Credit: 13 hours Category 1 AMA
Fee: \$295
Info: 415/476-5808

April 9-11

Current Concepts in Vascular Surgery
Place: Philadelphia, PA
Info: Fay Zelle, Hahnemann University, Broad and Vine Streets, M.X. 623, Philadelphia, PA 19102. 215/448-8263

April 10-12

OB/GYN and Abdominal Sonography: Update '87
Place: San Francisco, CA
Credit: 14.5 hours Category 1 AMA
Fee: \$325
Info: 415/476-5808

April 10-12

5th Annual MCV Symposium: New Trends in Anesthesia
Place: Williamsburg, VA
Fee: \$275
Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 10-12

22nd Annual Pediatric Springfest
Place: Williamsburg, VA
Fee: \$250
Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 12-18

Pathology Update 1987: Review of Current Concepts and New Developments
Place: Baltimore, MD
Info: American Society of Clinical Pathologists, 800/621-4142 (in IL 312/738-4890)

April 16-17

Current Topics in Trauma
Place: Johnson City, TN
Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

April 18-25

9th Diving Accident/Hyperbaric Oxygen Treatment Course
Place: Grand Cayman Island, BWI
Credit: 24 hours Category 1, AMA
Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878; outside NC 800/222-9984

April 23-25

Update in Cardiology: Recent Trends and Controversies
Place: Johnson City, TN
Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

April 23-25

23rd Annual Postgraduate Course in Radiology: The Chest
Place: Richmond, VA
Fee: \$325
Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 24-25

The Terminally Ill Patient: Psychological, Social, Legal, and Ethical Issues
Place: Boston, MA
Info: Harvard Medical School, Dept. of CME, Boston, MA 02115. 617/732-1525

April 24-26

9th Annual Conference on Emergency Medicine for the Primary Care Physician
Place: Williamsburg, VA
Fee: \$295
Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 24-26

7th Annual Clinical Concerns in Primary Care: Office Cardiology
Place: Williamsburg, VA
Fee: \$295
Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

April 27-May 2 (and March 2-7)

22nd Annual Family Practice Symposium

Place: Augusta, GA

Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

April 29

Acute Care Problems in Family Practice

Place: Johnson City, TN

Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

April 30-May 2

Clinical Nuclear Cardiology: Case Review with the Experts

Place: Bethesda, MD

Credit: 21.5 hours Category I AMA

Fee: \$415-465

Info: American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 800/253-4636 (in MD, 301/897-5400, ext 241)

April 30-May 3

North American Society of Pacing and Electrophysiology

Place: Boston, MA

Credit: 16 hours Category I AMA (for General Sessions)

Fee: \$90-215

Info: NASPE Registration, 13 Eaton Court, Wellesley Hills, MA 02181. 617/237-1866

May 2-9

Doppler and 2-D Echocardiography

Place: Newport Beach, CA

Fee: \$895 approx.

Credit: 40 hours Category I AMA

Info: Lisa Krehbiel, Institute for Medical Studies, 30131 Town Center Dr., Ste. 215, Laguna Niguel, CA 92677. 714/495-4499

May 8-10

6th Annual MCV Cardiology Conference

Place: Williamsburg, VA

Fee: \$325

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

May 11-15

Consultant's Course in Cardiology

Place: New York, NY

Credit: 32 hours Category I AMA

Fee: \$425 ACC members; \$525 others

Info: Registration Secretary, Extramural Programs Dept., American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 800/253-4636; MD & AK, 301/897-5400 ext 226

May 14-16

Vascular Surgery 1987: Third International Vascular Symposium

Place: New York, NY

Fee: \$400

Credit: 24 hours Category I AMA

Info: Ann J. Boehme, Assoc. Director for CME, Long Island Jewish Medical Center, New Hyde Park, NY 11042. 718/470-8650

May 15

3rd Annual Symposium on Geriatric Medicine

Place: Norfolk, VA

Credit: 5 hours Category I AMA

Fee: \$35-55

Info: Elaine Halverson, EVMS-CME, P.O. Box 1980, Norfolk, VA 23501. 804/446-5243

May 17

Annual Meeting, NC Chapter of American College of Surgeons

Place: Myrtle Beach, SC

Credit: 8 hours Category I AMA

Fee: \$50

Info: Michael C. Rowland, M.D., F.A.C.S., Secretary-Treasurer, NC-ACS, P.O. Box 2000, Pinchurst 28374. 919/295-2232

May 18-19

14th Annual Hans Berger Day and EEG Symposium

Place: Richmond, VA

Fee: \$250

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

May 19-22

Cell Calcium Metabolism '87: Physiology, Biochemistry, Pharmacology, and Clinical Implications

Place: Washington, D.C.

Info: Dr. Gary Fiskum, Dept. of Biochemistry, The George Washington University of Medicine and Health Sciences, 2300 Eye St. NW, Washington, D.C. 20037.

May 22-24

2nd Annual Duke Anesthesiology Conference: Oxygen Transport in the Clinical Setting

Place: Charleston, SC

Credit: 13 hours Category I AMA

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878; outside NC 800/222-9984

May 23-25

Gynecologic Urology and Pelvic Surgery

Place: Williamsburg, VA

Fee: \$260

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

May 26-30

Fifth Annual Cardiology Update

Place: Honolulu, HI

Fee: \$395

Info: Lisa Krehbiel, 30131 Town Center Dr., Ste. 215, Laguna Niguel, CA 92677. 714/495-4499

May 30

Management of Tough Problems in Psychiatric Practice

Place: Gatlinburg, TN

Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

May 30-June 2

International Conference on Missionary Medicine

Place: St. Simons Island, GA

Fee: \$100-225

Info: Registrar, ICMM, MAP International, Box 50, Brunswick, GA 31520. 912/265-6010, ext 321

June 1-5

Basic Mechanisms of Cardiovascular Diseases: Implications for Prevention and Therapy

Place: London, England

Credit: 26 hours Category I AMA

Fee: \$425

Info: London Cardiology Course, Div. of CME-Vanderbilt, CCC-5326 Medical Center North, Nashville, TN 37232. 615/322-4030

June 3-7

Eleventh Annual Postgraduate Course on Rehabilitation of the Brain-Injured Adult and Child

Place: Williamsburg, VA

Fee: \$285

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Station, Richmond, VA 23298-0001. 804/786-0494

June 4-6

11th Annual Update Cardiology for the Primary Physician

Place: Charleston, SC

Credit: 19 Hours Category I AMA

Fee: \$335-400

Info: Registration Secretary, Extramural Programs Dept., American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 800/253-4636 (in MD and AK, 301/897-5400, ext 226)

June 5-7

16th Annual Scientific Assembly, CA Chapter of American College of Emergency Physicians

Place: Newport Beach, CA

Fee: \$250 non-members

Info: CAL/ACEP, 505 N. Sepulveda Blvd., #12-14, Manhattan Beach, CA 90266. 213/374-4039

June 6-11

Advanced Techniques in MRI

Place: Kiawah Island, SC

Credit: 14 hours Category I AMA

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878; outside NC 800/222-9984

June 8-10

Aggressive Management of Cardiovascular Emergencies
 Place: Bethesda, MD
 Credit: 17 hours Category I AMA
 Fee: \$415 members ACC; \$465 others
 Info: Program Registrar, Heart House Learning Center, American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 301/897-5400, ext 241; 800/253-4636

June 9-13

4th Annual Adult Infectious Disease Seminar — Current Update
 Place: Hilton Head Island, SC
 Credit: 19 hours Category I AMA. AAFP
 Fee: \$295
 Info: George M. Converse, M.D., Director, Medical Education, Lloyd Noland Hospital and Health Centers, 701 Ridgeway Rd., Fairfield, AL 35064. 800/845-6131 (in SC, 800/922-7042)

June 10-13

Post-Graduate Course: Dermatology for Non-Dermatologists
 Place: Myrtle Beach, SC
 Credit: 15.5 hours Category I AMA
 Fee: \$200-350
 Info: Div. of Dermatology, Box 3135, Duke University Medical Center, Durham 27710. 919/684-2504

June 11-13

Advanced Echocardiography and Doppler Ultrasound 1987
 Place: San Diego, CA
 Credit: 21 hours Category I AMA
 Fee: \$295-450
 Info: Registration Secretary, Extramural Programs Dept, American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 301/897-5400, ext 241; 800/253-4636

June 11-13

Current Advances in Pediatric Practice
 Place: Gatlinburg, TN
 Credit: 12 hours Category I/II/III, AAP, AAFP
 Info: Dr. Sandra Loucks, University of Tennessee Memorial Research Center and Hospital, Dept. of Pediatrics, 1924 Alcoa Highway, Knoxville, TN 37920. 615/544-9331

June 15-17

Management of Clinically Localized Prostate Cancer
 Place: Bethesda, MD
 Credit: 14 hours Category I AMA
 Info: Nancy Cowan, Prospect Associates, 1801 Rockville Pike, Suite 500, Rockville, MD 20852. 301/468-6555

June 15-18

18th Annual Internal Medicine Symposium
 Place: Kiawah Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

June 15-18

4th Annual Advanced Colposcopy and Basic and Advanced Gynecologic Laser Surgery
 Place: Hilton Head, SC
 Info: Educational Associates, P.O. Box 24772, Winston-Salem 27114. 919/760-2788

June 21-28

3rd Annual Advances in Internal Medicine
 Place: Hilton Head Island, SC
 Credit: 25 hours Category I AMA
 Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878; outside NC 800/222-9984

July 9-11

Clinical Obstetrics
 Place: Kiawah Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

July 13-16

Clinical Cardiology
 Place: Kiawah Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

July 16-18

3rd Annual Berkshire Medical Conference: Advances in Cardiology
 Place: Hancock, MA
 Credit: 16 hours Category I AMA
 Fee: \$295
 Info: Berkshire AHEC, 725 North St., Pittsfield, MA 01201. 413/499-4161, ext 2417

July 17-19

Practical Internal Medicine: Selected Topics for the Internist
 Place: Virginia Beach, VA
 Fee: \$295
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Station, Richmond, VA 23298-0001

July 22-26

Critical Care Medicine
 Place: Kiawah Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

July 23-25

3rd Annual Berkshire Medical Conference: Common Emergencies in General Medicine
 Place: Hancock, MA
 Credit: 16 hours Category I AMA
 Fee: \$295
 Info: Berkshire AHEC, 725 North St., Pittsfield, MA 01201. 413/499-4161, ext 2417

July 27-29

Pediatric Update 1987
 Place: Kiawah Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

July 31-August 2

The 9th Annual Pediatric Primary Care Conference: Pediatrics at the Beach
 Place: Virginia Beach, VA
 Fee: \$275
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Station, Richmond, VA 23298-0001

August 2-7

Diagnostic Electron Microscopy: Annual Meeting, Electron Microscopy Society of America
 Place: Baltimore, MD
 Info: John Shelburne, M.D., or Victor Roggli, M.D., Dept. of Pathology, Duke University and V.A. Medical Centers, Durham 27710. 919/286-6925

August 3-8

Your Practice, Your Money, Your Family
 Place: Hilton Head Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

August 6-9

Summer Retreat: Practical Issues in Primary Care
 Place: Virginia Beach, VA
 Fee: \$350
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48 MCV Station, Richmond, VA 23298-0001. 804/786-0494

August 14-16

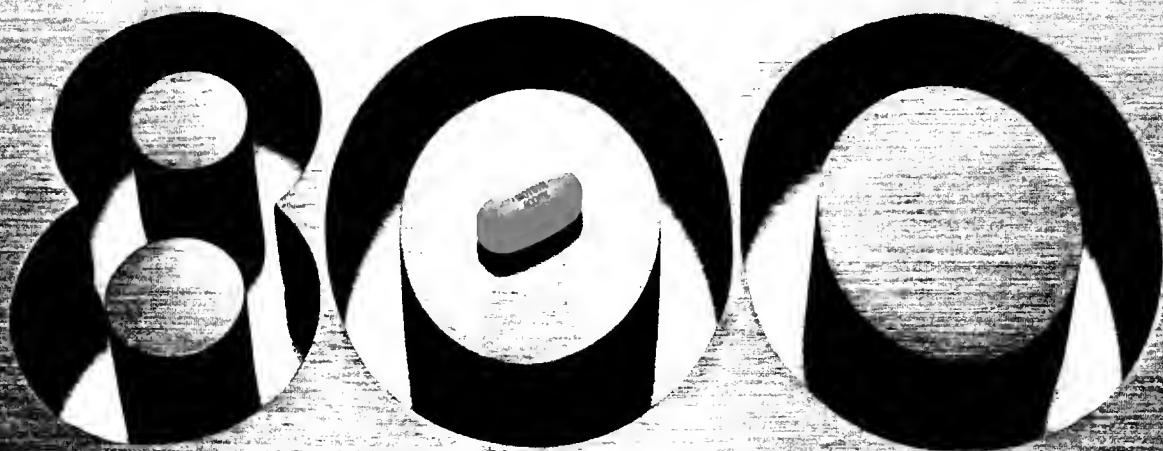
Primary Care of the Female Patient
 Place: Virginia Beach, VA
 Fee: \$295
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48 MCV Station, Richmond, VA 23298-0001. 804/786-0494

August 15

Seminar on Geriatrics
 Place: Abingdon, VA
 Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

Motrin[®] 800 TABLETS **mg**

ibuprofen



**Extra Strength
Convenience
Economy**



A Century
of Caring
1886-1986



There's never been
a better time for her...
and
PREMARIN[®]
(Conjugated Estrogens Tablets)

Now the evidence looks better than ever

Significantly reduced risk of endometrial hyperplasia

Endometrial hyperplasia was significantly reduced when progestin was added to PREMARIN therapy for more than ten days a month.¹⁻⁴ The risk of endometrial hyperplasia may also be reduced through cyclic administration of unopposed, low-dose PREMARIN.

Effect on lipids—an important feature

PREMARIN used alone does not adversely affect lipid levels. In fact, a clinical study has shown a significant increase in HDL cholesterol—from 49.7 mg/dL to 56.4 mg/dL—and decrease in LDL cholesterol—from 165.1 mg/dL to 138.1 mg/dL—after one year of therapy with PREMARIN, 0.625 mg.⁵

Low-dose control of menopausal symptoms*

PREMARIN effectively relieves vasomotor symptoms, such as hot flashes. When estrogen deficiency is limited to atrophic vaginitis, PREMARIN® (conjugated estrogens) Vaginal Cream restores the vaginal environment to its premenopausal state.

The most widely used, most extensively studied estrogen worldwide.

PREMARIN®
(Conjugated Estrogens Tablets)

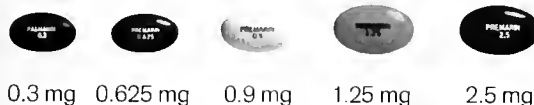
Most trusted for more reasons

*PREMARIN is indicated for moderate-to-severe vasomotor symptoms.

Please see following page for brief summary of prescribing information.

For moderate-to-severe
vasomotor symptoms

PREMARIN® (Conjugated Estrogens Tablets)



The appearance of these tablets is a trademark of Ayerst Laboratories.

For atrophic vaginitis

PREMARIN® (Conjugated Estrogens)

Vaginal
Cream

0.625mg/g



BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION AND PATIENT INFORMATION, SEE PACKAGE CIRCULARS)

PREMARIN® Brand of conjugated estrogens tablets, USP

PREMARIN® Brand of conjugated estrogens Vaginal Cream in a nonfluorinated base

1 ESTROGENS HAVE BEEN REPORTED TO INCREASE THE RISK OF ENDOMETRIAL CARCINOMA

Three independent case control studies have reported an increased risk of endometrial cancer in postmenopausal women exposed to exogenous estrogens for more than one year. This risk was independent of the other known risk factors for endometrial cancer. These studies are further supported by the finding that incidence rates of endometrial cancer have increased sharply since 1969 in eight different areas of the United States with population-based cancer reporting systems, an increase which may be related to the rapidly expanding use of estrogens during the last decade. The three case control studies reported that the risk of endometrial cancer in estrogen users was about 4.5 to 13.9 times greater than in nonusers. The risk appears to depend on both duration of treatment and on estrogen dose. In view of these findings, when estrogens are used for the treatment of menopausal symptoms, the lowest dose that will control symptoms should be utilized and medication should be discontinued as soon as possible. When prolonged treatment is medically indicated, the patient should be reassessed on at least a semiannual basis to determine the need for continued therapy. Although the evidence must be considered preliminary, one study suggests that cyclic administration of low doses of estrogen may carry less risk than continuous administration; it therefore appears prudent to utilize such a regimen. Close clinical surveillance of all women taking estrogens is important. In all cases of undiagnosed persistent or recurring abnormal vaginal bleeding, adequate diagnostic measures should be undertaken to rule out malignancy. There is no evidence at present that "natural" estrogens are more or less hazardous than "synthetic" estrogens at equieffective doses.

2 ESTROGENS SHOULD NOT BE USED DURING PREGNANCY

The use of female sex hormones, both estrogens and progestogens, during early pregnancy may seriously damage the offspring. It has been shown that females exposed in utero to diethylstilbestrol, a non-steroidal estrogen, have an increased risk of developing in later life a form of vaginal or cervical cancer that is ordinarily extremely rare. This risk has been estimated as not greater than 4 per 1,000 exposures. Furthermore, a high percentage of such exposed women (from 30% to 90%) have been found to have vaginal adenosis, epithelial changes of the vagina and cervix. Although these changes are histologically benign, it is not known whether they are precursors of malignancy. Although similar data are not available with the use of other estrogens, it cannot be presumed they would not induce similar changes. Several reports suggest an association between intrauterine exposure to female sex hormones and congenital anomalies, including congenital heart defects and limb reduction defects. One case control study estimated a 4.7-fold increased risk of limb reduction defects in infants exposed in utero to sex hormones (oral contraceptives, hormone withdrawal tests for pregnancy, or attempted treatment for threatened abortion). Some of these exposures were very short and involved only a few days of treatment. The data suggest that the risk of limb reduction defects in exposed fetuses is somewhat less than 1 per 1,000. In the past, female sex hormones have been used during pregnancy in an attempt to treat threatened or habitual abortion. There is considerable evidence that estrogens are ineffective for these indications, and there is no evidence from well controlled studies that progestogens are effective for these uses. If PREMARIN is used during pregnancy, or if the patient becomes pregnant while taking this drug, she should be apprised of the potential risks to the fetus, and the advisability of pregnancy continuation.

DESCRIPTION: PREMARIN (conjugated estrogens, USP) contains a mixture of estrogens, obtained exclusively from natural sources, blended to represent the average composition of material derived from pregnant mares' urine. It contains estrone, estradiol, and 17 α -dihydroestrone together with smaller amounts of 17 α -estradiol, equilin, and 17 α -dihydroequilin as salts of their sulfate esters. Tablets are available in 0.3 mg, 0.625 mg, 0.9 mg, 1.25 mg, and 2.5 mg strengths of conjugated estrogens. Cream is available as 0.625 mg conjugated estrogens per gram.

INDICATIONS AND USAGE: PREMARIN (conjugated estrogens tablets, USP): Moderate-to-severe vasomotor symptoms associated with the menopause. (There is no evidence that estrogens are effective for nervous symptoms or depression without associated vasomotor symptoms and they should not be used to treat such conditions.) Osteoporosis (abnormally low bone mass). Atrophic vaginitis. Kraurosis vulvae. Female castration.

PREMARIN (conjugated estrogens) Vaginal Cream is indicated in the treatment of atrophic vaginitis and kraurosis vulvae. PREMARIN HAS NOT BEEN SHOWN TO BE EFFECTIVE FOR ANY PURPOSE DURING PREGNANCY AND ITS USE MAY CAUSE SEVERE HARM TO THE FETUS (SEE BOXED WARNING).

Concomitant Progestin Use: The lowest effective dose appropriate for the specific indication should be utilized. Studies of the addition of a progestin for 7 or more days of a cycle of estrogen administration have reported a lowered incidence of endometrial hyperplasia. Morphological and biochemical studies of the endometrium suggest that 10 to 13 days of progestin are needed to prevent maturation of the endometrium and to eliminate any hyperplastic changes. Whether this will provide protection from endometrial carcinoma has not been clearly established. There are possible additional risks which may be associated with the inclusion of progestin in estrogen replacement regimens. (See PRECAUTIONS.) The choice of progestin and dosage may be important; product labeling should be reviewed to minimize possible adverse effects.

CONTRAINDICATIONS: Estrogens should not be used in women (or men) with any of the following conditions: 1 Known or suspected cancer of the breast except in appropriately selected patients being treated for metastatic disease. 2 Known or suspected cancer of the endometrium. 3 Known or suspected pregnancy. (See Boxed Warning.) 4 Undiagnosed abnormal genital bleeding. 5 Active thrombophlebitis or thromboembolic disorders. 6 A past history of thrombophlebitis, thrombosis, or thromboembolic disorders associated with previous estrogen use (except when used in treatment of breast or prostatic malignancy).

WARNINGS: Long-term, continuous administration of natural and synthetic estrogens in certain animal species increases the frequency of carcinomas of the breast, cervix, vagina, and liver. There are now reports that estrogens increase the risk of carcinoma of the endometrium in humans. (See Boxed Warning.) At the present time there is no satisfactory evidence that estrogens are effective for postpartum breast enlargement. Use of oral contraceptives has an increased risk of diseases, such as thrombophlebitis, pulmonary embolism, stroke, and myocardial infarction. Cases of retinal thrombosis, mesenteric thrombosis, and optic neuritis have been reported in oral contraceptive users. An increased risk of postsurgery thromboembolic complications has also been reported in users of oral contraceptives. If feasible, estrogen should be discontinued at least 4 weeks before surgery of the type associated with an increased risk of thromboembolism, or during periods of prolonged immobilization. Estrogens should not be used in persons with active thrombophlebitis, thromboembolic disorders, or in persons with a history of such disorders in association with estrogen use. They should be used with

caution in patients with cerebral vascular or coronary artery disease. Large doses (5 mg conjugated estrogens per day), comparable to those used to treat cancer of the prostate and breast, have been shown to increase the risk of nonfatal myocardial infarction, pulmonary embolism and thrombophlebitis. When doses of this size are used, any of the thromboembolic and thrombotic adverse effects should be considered a clear risk.

Benign hepatic adenomas should be considered in estrogen users having abdominal pain and tenderness, abdominal mass, or hypovolemic shock. Hepatocellular carcinoma has been reported in women taking estrogen-containing oral contraceptives. Increased blood pressure may occur with use of estrogens in the menopause and blood pressure should be monitored with estrogen use. A worsening of glucose tolerance has been observed in patients on estrogen-containing oral contraceptives. For this reason, diabetic patients should be carefully observed. Estrogens may lead to severe hypercalcemia in patients with breast cancer and bone metastases.

PRECAUTIONS: Physiological examination and a complete medical and family history should be taken prior to the initiation of any estrogen therapy with special reference to blood pressure, breasts, abdomen and pelvic organs, and should include a Papanicolaou smear. As a general rule, estrogen should not be prescribed for longer than one year without another physical examination being performed. Conditions influenced by fluid retention such as asthma, epilepsy, migraine, and cardiac or renal dysfunction, require careful observation. Certain patients may develop manifestations of excessive estrogenic stimulation, such as abnormal or excessive uterine bleeding, mastitis, etc. Prolonged administration of unopposed estrogen therapy has been reported to increase the risk of endometrial hyperplasia in some patients. Oral contraceptives appear to be associated with an increased incidence of mental depression. Patients with a history of depression should be carefully observed. Increasing uterine leiomyomata may increase in size during estrogen use. The pathologist should be advised of estrogen therapy when relevant specimens are submitted. If jaundice develops in any patient receiving estrogen, the medication should be discontinued while the cause is investigated. Estrogens should be used with care in patients with impaired liver function, renal insufficiency, metabolic bone diseases associated with hypercalcemia, or in young patients in whom bone growth is not complete. If concomitant progestin therapy is used, potential risks may include adverse effects on carbohydrate and lipid metabolism.

The following changes may be expected with larger doses of estrogen:

- a Increased sulfobromophthalen retention
- b Increased prothrombin and factors VII, VIII, IX, and X, decreased antithrombin 3; increased non-epinephrine-induced platelet aggregability
- c Increased thyroid binding globulin (TBG) leading to increased circulating total thyroid hormone, as measured by T₄ by column, or T₄ by radioimmunoassay. Free T₄ resin uptake is decreased, reflecting the elevated TBG; free T₄ concentration is unaltered
- d Impaired glucose tolerance
- e Decreased pregnandiol excretion
- f Reduced response to metoprolol test
- g Reduced serum folate concentration
- h Increased serum triglyceride and phospholipid concentration

As a general principle, the administration of any drug to nursing mothers should be done only when clearly necessary since many drugs are excreted in human milk.

ADVERSE REACTIONS: The following have been reported with estrogenic therapy, including oral contraceptives: breakthrough bleeding, spotting, change in menstrual flow, dysmenorrhea, premenstrual-like syndrome, amenorrhea during and after treatment, increase in size of uterine leiomyomata, vaginal candidiasis, change in cervical erosion and in degree of cervical secretion, cystitis-like syndrome, tenderness, enlargement, secretion (of breasts), nausea, vomiting, abdominal cramps, bloating, cholestatic jaundice, chloasma or melasma which may persist when drug is discontinued, erythema multiforme, erythema nodosum, hemorrhagic eruption, loss of scalp hair, hirsutism, sleeping of corneal contact, intolerance to contact lenses, headache, migraine, dizziness, mental depression, changes in libido.

ACUTE OVERDOSEAGE: May cause nausea, and withdrawal bleeding may occur in females.

DOSEAGE AND ADMINISTRATION:

PREMARIN® Brand of conjugated estrogens tablets, USP

1. Given cyclically for short-term use only. For treatment of moderate to severe vasomotor symptoms, atrophic vaginitis, or kraurosis vulvae associated with the menopause (0.3 to 2.5 mg or more daily). The lowest dose that will control symptoms should be chosen and medication should be discontinued as promptly as possible. Administration should be cyclic (eg, three weeks on and one week off). Attempts to discontinue or taper medication should be made at three- to six-month intervals.

2. Given cyclically. Female castration. Osteoporosis. Female castration—1.25 mg daily, cyclically. Adjust upward or downward according to response of the patient. For maintenance, adjust dosage to lowest level that will provide effective control. Osteoporosis—0.625 mg daily. Administration should be cyclic (eg, three weeks on and one week off).

Patients with an intact uterus should be monitored for signs of endometrial cancer and appropriate measures taken to rule out malignancy in the event of persistent or recurring abnormal vaginal bleeding.

PREMARIN® Brand of conjugated estrogens Vaginal Cream

Given cyclically for short-term use only. For treatment of atrophic vaginitis or kraurosis vulvae.

The lowest dose that will control symptoms should be chosen and medication should be discontinued as promptly as possible.

Administration should be cyclic (eg, three weeks on and one week off).

Attempts to discontinue or taper medication should be made at three- to six-month intervals.

Usual dosage range: 2 to 4 g daily, intravaginally, depending on the severity of the condition.

Treated patients with an intact uterus should be monitored closely for signs of endometrial cancer and appropriate diagnostic measures should be taken to rule out malignancy in the event of persistent or recurring abnormal vaginal bleeding.

References:

1. Whitehead MI, Townsend PT, Pryse-Davies J, et al: Effects of estrogens and progestins on the biochemistry and morphology of the postmenopausal endometrium. *N Engl J Med* 1981;305:1599-1605. 2. Paterson ME, Wade-Evans T, Sturdee OW, et al: Endometrial disease after treatment with estrogens and progestins in the climacteric. *Br Med J* 1980;280:822-824. 3. Magos AL, Brincat M, Studd JWW, et al: Amenorrhea and endometrial atrophy with continuous oral estrogen and progestogen therapy in postmenopausal women. *Obstet Gynecol* 1985;67:496-499. 4. Whitehead MI, Lane G, Siddie N, et al: Avoidance of endometrial hyperstimulation in estrogen-treated postmenopausal women. *Semin Reprod Endocrinol* 1993;11:41-52. 5. Barnes RB, Roy S, Lobo RA: Comparison of lipid and androgen levels after conjugated estrogen or depo-medroxyprogesterone acetate treatment in postmenopausal women. *Obstet Gynecol* 1985;66:216-219.

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T6194/BB6

OFFICIAL CALL HOUSE OF DELEGATES

HOUSE OF DELEGATES Meetings Scheduled

Notice to: Delegates, Alternate Delegates, Officials of the North Carolina Medical Society, and Presidents and Secretaries of county medical societies.

Sessions of the HOUSE OF DELEGATES will convene in the Cardinal Ballroom, Pinehurst Hotel, Pinehurst, North Carolina, at the following times:

Thursday, April 30, 1987 — 9:30 a.m. — Opening Session

Saturday, May 2, 1987 — 2:00 p.m. — Second Session

A member of the CREDENTIALS COMMITTEE will be present at the Desk in the West Lobby, Wednesday, April 29, 1987, 3:00 p.m. to 5:00 p.m., and Thursday, April 30, 1987, 8:30 a.m. to 10:00 a.m. to certify Delegates. Delegates are urged to bring their Credential Cards for presentation at the Registration Desk. Delegate Badges must be worn to be seated in the HOUSE OF DELEGATES.

REFERENCE COMMITTEE HEARINGS

Reference Committee hearings are scheduled to begin Thursday, April 30, 1987, at 2:00 p.m.

JOHN W. FOUST, M.D., President
HENRY J. CARR, JR., M.D., President-Elect
T. REGINALD HARRIS, M.D., Speaker
JOHN A. FAGG, M.D., Vice-Speaker
JOHN T. DEES, M.D., Secretary
GEORGE E. MOORE, Executive Vice-President

In Memoriam

Angus Murdoch McBryde, M.D.

Angus Murdoch McBryde was born in Raeford, North Carolina May 25, 1902 and died unexpectedly in Durham September 16, 1986 while visiting a friend. He was graduated from Davidson College in 1924 and the University of Pennsylvania School of Medicine in 1928. His residency was served at the University of Pennsylvania and Johns Hopkins. He came to Duke University School of Medicine in early 1931 and was a member of the original pediatric faculty at the newly founded medical school where his chief interest was neonatology. He started the Special Care Nursery. His contributions there have been recognized by the annual Angus M. McBryde Perinatal Symposium for the past thirty-one years, the Kenan-McBryde endowed Fellowship in neonatology, and the distinguished Medical Alumni award for excellence in teaching. He retired from Duke in 1972.

In 1935 he started a private practice of pediatrics in Durham combining that work with his active faculty work at Duke. In 1949 he was joined by Dr. Bailey Webb and later by Drs. Clarence Bailey and Jean Findlay. He retired from both in 1981. He was past president of the Durham-Orange County Medical Society and North Carolina Pediatric Society, and was a member of the American Medical Association, North Carolina Medical Society, American Academy of Pediatricians and Society for Pediatric Research.

He was an active member of the Kiwanis Club for fifty years. A devout member of St. Phillips Episcopal Church, he served as senior warden and on the vestry on numerous occasions. He was very active in the establishment of the soup kitchen and the building of the Urban Ministries facility. After retirement, he and his wife, Priscilla Gregory McBryde, served as Co-Chairman of the Durham Historic Preservation Society. An avid sports fan, he enjoyed playing golf until his death. He was a devoted husband and father and a man of many friends. In 1975 he was named a Father of the Year in Durham.

Quoting Dr. Lenox Baker in the *Durham Morning Herald*, "Dr. McBryde as a man could stand out in a crowd without being conspicuous. He exuded a certain presence: knowledge of medicine, care for his students and especially his patients and a variety of interests.

"What interested him most though were people. He had a large heart for helping others, whether through medicine or community service —

"Today's generation of doctors and students at Duke can look back on the career of Dr. McBryde and say, as Sir Isaac Newton did, that they see far afield because they stood on the shoulder of giants. He was one."

He is survived by his wife, three children, Dr. Angus M.

McBryde, Jr., Neill Gregory McBryde, Mrs. James T. Spence, III and ten grandchildren.

Walter J. Loehr, M.D.

President

Durham-Orange County Medical Society

Perry Belton Clark, M.D.

Perry Clark burned as brightly as it was possible for a person to burn. He was a devoted and loving husband and father, a highly skilled physician with consummate compassion, and an understanding and giving friend.

Perry Clark died on Sunday, November 30, 1986 at Forsyth Memorial Hospital where he had been since suffering a massive cerebral hemorrhage while jogging on November 27, 1986. Perry was born on April 30, 1939 in Louisville, Kentucky to Robert F. and Louise P. Clark. He grew up in Louisville and graduated college at Princeton University. He returned to the University of Kentucky Medical School where he received his M.D. and then served his internship at UCLA. Perry then came to Winston-Salem and did his training in obstetrics and gynecology at North Carolina Baptist Hospital and Bowman Gray School of Medicine. He finished this residency in 1972 and joined the Lyndhurst Gynecologic Associates and had practiced as a member of that group throughout his career.

Perry was a dynamic member of the Lutheran Church of the Epiphany and was also a member of Old Town Club and the downtown Rotary Club. He was a tireless worker and a major force in the Planned Parenthood organization in this area and was largely responsible for the successful fund raising efforts for this organization. We all remember the tenacity of his fund raising and promotional efforts.

During this past year Perry was taking part in the Leadership Winston-Salem activities and at the time of his death was about to be named President Elect of the Forsyth County Medical Society. Perry had devoted a great deal of time over the past several years working on public relations for the Medical Society because he was concerned about the public image of physicians in Winston-Salem.

This great bear of a man affected and inspired all of us. He faced setbacks which would have subdued a lesser being and came back driving even harder. None of us will forget his contagious laugh, his often moist eyes triggered by the real stuff of life, his unconditional love for people from all walks of life, and his innate compassion and nurturing for those in pain and doubt.

It is now our job to continue, and keep alive, what Perry Clark represented.

Forsyth-Stokes-Davie County Medical Society

Ray Donald Minges, M.D.

On August 15, 1920, in Catawba County, N.C., Ray Donald Minges entered this world. His family subsequently moved to Greenville where, with his parents, brothers and sister, he helped build the Pepsi-Cola Company in this area by working before and after school hours. Following grad-

uation from high school, he entered and was graduated from Davidson College in 1941. In 1944 he was graduated from the Medical College of Virginia Commonwealth University School of Medicine. Ray's post graduate training included an Internship and first year Residency in General Surgery at Johnson-Willis Hospital in Richmond, Virginia. From 1946 to 1948 he served as a Medical Officer with the U.S. Army in Alaska and the Aleutian Islands. From 1948 to 1950 he returned to Johnson-Willis Hospital and served as a Resident in Internal Medicine. From July 1950 through September 1953 he completed his training in General Surgery at the Medical College of Virginia Hospital. Upon his return to Greenville he entered into the practice of General Surgery until his retirement in 1970.

Dr. Minges was one of the first to usher in the era of specialization in practice in Eastern North Carolina. He was active in the Pitt County Medical Society and served as Chief of Staff at Pitt County Memorial Hospital. Ray was a strong supporter of the continued development of medicine and medical services in this area.

As a physician, Ray exhibited a sincere interest in the care and well-being of his patients. On many occasions, he impressed us with his deep thought and thorough consideration of all possible diagnoses prior to performing surgery on a patient — a quality, I like to think, he acquired as a resident in Internal Medicine. He was an excellent surgeon and physician, who knew his limitations and had no reservations about recommending that a better qualified colleague manage any patient beyond his capabilities. He was always the first to admit any error in judgment.

As a person, Dr. Minges freely gave of his time, knowledge, energy, and money to innumerable projects in the Greenville Community. Ray had the ability to recognize promise in young people and on many occasions made financial assurance that they were able to receive a college education. Ray had an abiding faith and trust in his God which provided him with an immense inner strength. It was this faith and strength that enabled him to endure several personal tragedies in his life, and face the inevitable with courage and inner peace. His spectrum of friends was wide and reflected his interest in education, hunting, sports, church and community. He was known to one and all as Ray.

Dr. Minges viewed death as he did graduation — not an end but a beginning. On January 19, 1987, Ray departed this life to join his daughter Barbara and son Donald who had preceded him.

Mrs. Virginia Minges has lost a loving husband; Tom, Pat and Ginger have lost an adoring father; the Community has lost a magnanimous benefactor; East Carolina University has lost a tireless supporter and fund raiser; Medicine has lost a sensitive and caring physician; and those of us who knew Dr. Ray Minges have lost a close and trusted friend.

If Ray had the opportunity to leave us collectively any parting comments, I believe he would say "Do not despair over my death, but rejoice in the life I had with you."

Eric Fearington, M.D.
Pitt County Medical Society

Our journal has a new look . . .

We thank the NCMJ Editorial Board, editorial assistant Jane Whalen, and our printer The Ovid Bell Press, Inc., for their contributions.

The Editor and Managing Editor

Dear Colleague:

I am preparing to release to the public an STD profile including HTLV-III antibodies, Hepatitis B Surface Antigen, Chlamydia IFA antibodies, and Syphilis RPR. This profile will be known as AIDCARD[™] and will cost \$60. Western Blot will be done on all positive HTLV-III tests and FTA on all positive RPR. These will be done by a highly reputable and licensed and certified reference laboratory located in North Carolina.

The positive tests will generate a group of concerned citizens who will be seeking your evaluation of the meaning of those positive tests. We recognize that the chlamydia antibody test will be positive in a large number of people who are not infectious. We decided to make this a part of the profile because it would identify a group at risk and bring these people to you for a proper search for other STD's. If you evaluate these people and find that they are not contagious and will write us to that effect, we will issue them an AIDCARD[™].

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There are limitations and shortcomings to this undertaking, the primary ones being those trade-offs between our public-health desire for case finding and the individual's right to privacy. Any way you can help to resolve these dilemmas with each individual will be a great service. Any suggestions for improvement in our program will receive careful attention. Your support, both publicly and privately, will be greatly appreciated. We expect such a profile to represent the standard of care at least for anyone with STD signs or symptoms.

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Index to Advertisers

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Allscrips Pharmaceuticals, Inc.	174	National Staffing Services Corp.	224
Ayerst Laboratories	180a-d, 232b-d	NCNB	173
B & B X-Ray, Inc.	198	Paradox Productions	216
Burroughs Wellcome Co.	190a-b, 191, 220	Physicians Practice Management	195
Campbell Laboratories, Inc.	189	Roche Laboratories ...	177-178, 192-193, 217, Cover 3-4
Communication Properties	201	Roerig	222b-d
Crompton Company	Cover 2	St. Albans Psychiatric Hospital	194
Eli Lilly & Company	200	Smith Kline & French	222a
Hinrichs Financial Group	176	The Upjohn Company	232a
Marion Laboratories	202a-b	Wake Medical Center	190
Medic Computer Systems	237	Winchester Surgical Supply Co.	240
Medical Mutual Insurance Company of N.C.	202		

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North Carolina Medical Journal

For Doctors and their Patients

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Contents Page 243



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For Doctors and their Patients

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North Carolina Medical Journal

FOR DOCTORS AND THEIR PATIENTS

Contents / May 1987, Volume 48, Number 5

Cover drawing by Irene Roderick, Durham YWCA

SCIENTIFIC ARTICLE

- 249 Percutaneous Balloon Valvuloplasty of Calcific Aortic Stenosis
Charles J. Davidson, Thomas N. Skelton, Katherine Kisslo, Robert H. Peter, Charles Simonton, Harry Phillips, Victor S. Behar, Yihong Kong, and Thomas M. Bashore

TOXIC ENCOUNTERS

- 258 Through All Thy Veins Shall Run a Cold and Drowsy Humor: Nightshade Poisoning
Ronald B. Mack

FOR PATIENTS

- 265 Teens and Sex: Confessions of an Imperiled Liberal *John F. Steege*
267 "American Teens Speak": Report on a Survey *Planned Parenthood Federation of America*
270 A Local Project To Reduce Teen Pregnancy *Pauline Frazier*
272 Beware the Devilfish *Harry H. Summerlin, Jr.*

SPECIAL ARTICLE

- 273 Physician Assistants in North Carolina, 1986: A Report on a Survey Sponsored by the North Carolina Academy of Physician Assistants *Dean L. Minton, David M. Coniglio, Jerry A. Heath, Jeffrey A. Katz, and Wayne W. Vonseggen*

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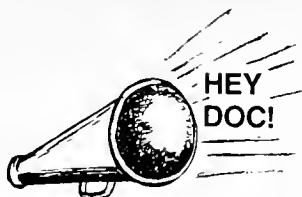
- 280 Reflections on Infections by the Sea, or Another Form of Seasickness *Paul Becherer*

POETRY

- 281 Medical Student's Disease Syndrome *Gary L. Roark*

BULLETIN BOARD

- | | | | |
|-----|------------------------------|-----|---------------------------|
| 283 | Letters to the Editor | 294 | Classified Advertisements |
| 289 | New Members | 295 | Instructions to Authors |
| 289 | Continuing Medical Education | 296 | Index to Advertisers |



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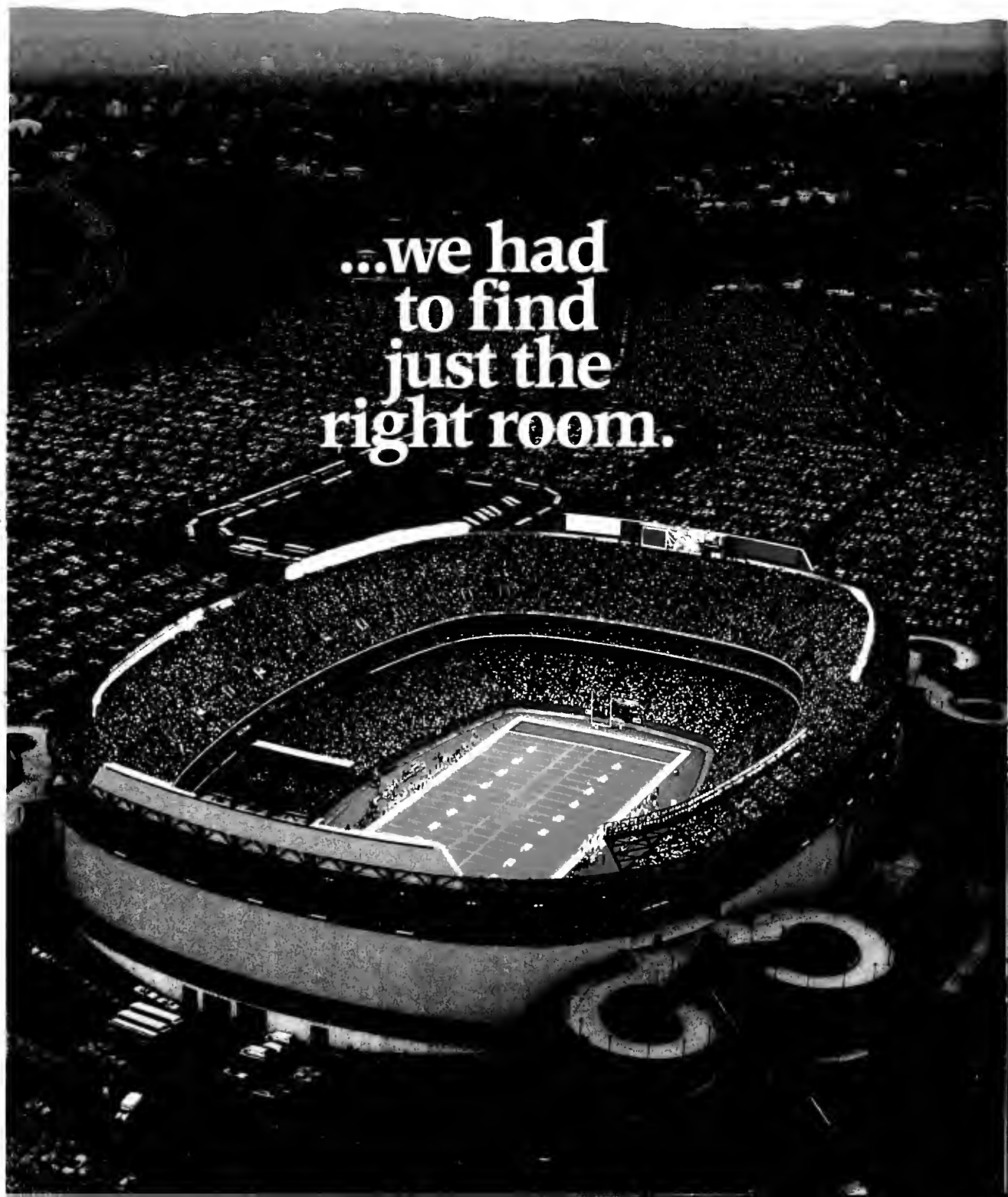
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Like conventional INDERAL Tablets, INDERAL LA should not be used in the presence of congestive heart failure, sinus bradycardia, cardiogenic shock, heart block greater than first degree, and bronchial asthma.

*After a 30-day trial with INDERAL LA, physicians reported that 90% of the patients would remain on INDERAL LA.

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keeps looking better**

Please see next page for brief summary of prescribing information



The one you know best keeps looking better

BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE CIRCULAR)

INDERAL® LA brand of propranolol hydrochloride (Long Acting Capsules)

DESCRIPTION. Inderal LA is formulated to provide a sustained release of propranolol hydrochloride. Inderal LA is available as 60 mg, 80 mg, 120 mg, and 160 mg capsules.

CLINICAL PHARMACOLOGY. Inderal is a nonselective, beta-adrenergic receptor-blocking agent that blocks the autonomic nervous system activity. It specifically competes with beta-adrenergic receptor-stimulating agents for available receptor sites. When access to beta-receptor sites is blocked by Inderal, the chronotropic, inotropic, and vasodilator responses to beta-adrenergic stimulation are decreased proportionately.

Inderal LA Capsules (60, 80, 120, and 160 mg) release propranolol HCl at a controlled and predictable rate. Peak blood levels following dosing with Inderal LA occur at about 6 hours and the apparent plasma half-life is about 10 hours. When measured at steady state over a 24-hour period the areas under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of Inderal Tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol resulting from the slower rate of absorption of propranolol. Over a twenty-four (24) hour period blood levels are fairly constant for about twelve (12) hours then decline exponentially.

Inderal LA should not be considered a simple mg-for-mg substitute for conventional propranolol as the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to Inderal LA from conventional propranolol, a possible need for retitration upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, Inderal LA has been therapeutically equivalent to the same mg dose of conventional Inderal, as assessed by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure and rate pressure product. Inderal LA can provide effective beta blockade for a 24-hour period.

INDICATIONS AND USAGE. **Hypertension:** Inderal LA is indicated in the management of hypertension. It may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. Inderal LA is not indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: Inderal LA is indicated for the long-term management of patients with angina pectoris.

Migraine: Inderal LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: Inderal LA is useful in the management of hypertrophic subaortic stenosis, especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. Inderal LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. Inderal is contraindicated in 1) cardiogenic shock, 2) sinus bradycardia and greater than first-degree block, 3) bronchial asthma, 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with Inderal.

WARNINGS. **CARDIAC FAILURE.** Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign of symptoms of cardiac failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely or Inderal should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and in some cases myocardial infarction, following abrupt discontinuance of Inderal therapy. Therefore, when discontinuance of Inderal is planned, the dosage should be gradually reduced over at least a few days, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If Inderal therapy is interrupted and exacerbation of angina occurs, it is usually advisable to reinstitute Inderal therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (eg, chronic bronchitis, emphysema) — PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. Inderal should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY. The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. If it should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

INDERAL (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, eg, dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOLYCEMIA. Beta blockers should be used with caution in diabetic patients if a beta-blocking agent is required. Beta blockers may mask tachycardia occurring with hypoglycemia, but other manifestations such as dizziness and sweating may not be significantly affected. Following insulin-induced hypoglycemia, propranolol may cause a delay in the recovery of blood glucose to normal levels.

THYROID DYSFUNCTION. Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol may change thyroid function tests, increasing T₄ and reversing T₃ and decreasing T₃.

IN PATIENTS WITH MOYER-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case, this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. **GENERAL.** Propranolol should be used with caution in patients with impaired hepatic or renal function. Inderal (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should

be told that Inderal may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

CLINICAL LABORATORY TESTS. Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS. Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if Inderal is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncope, attacks, or orthostatic hypotension.

Caution should be exercised when patients receiving a beta blocker are administered a calcium-channel blocking drug, especially intravenous verapamil, for both agents may depress myocardial contractility or atrioventricular conduction. On rare occasions, the concomitant intravenous use of a beta blocker and verapamil has resulted in serious adverse reactions, especially in patients with severe cardiomyopathy, congestive heart failure or recent myocardial infarction.

Aluminum hydroxide gel greatly reduces intestinal absorption of propranolol. Ethanol slows the rate of absorption of propranolol.

Phenyltolerophenol, and rifampin accelerate propranolol clearance.

Chlorpromazine, when used concomitantly with propranolol, results in increased plasma levels of both drugs.

Antipyrine and lidocaine have reduced clearance when used concomitantly with propranolol.

Thyroxine may result in a lower than expected T₃ concentration when used concomitantly with propranolol.

Cimetidine decreases the hepatic metabolism of propranolol, delaying elimination and increasing blood levels.

Theophylline clearance is reduced when used concomitantly with propranolol. **CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY.** Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

PREGNANCY. Pregnancy Category C. Inderal has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. Inderal should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS. Inderal is excreted in human milk. Caution should be exercised when Inderal (propranolol HCl) is administered to a nursing woman.

PEDIATRIC USE. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: Bradycardia, congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud type.

Central Nervous System: Light-headedness, mental depression manifested by insomnia, lassitude, weakness, fatigue, reversible mental depression progressing to cataplexy, visual disturbances, hallucinations, vivid dreams, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics. For immediate formulations, fatigue, lethargy and vivid dreams appear dose-related.

Gastrointestinal: Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: Bronchospasm.

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura. **Auto-immune:** In extremely rare instances, systemic lupus erythematosus has been reported.

Idiosyncratic: Alopecia, LE-like reactions, psoriasisiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Cutaneous and mucous membrane reactions involving the skin, sensory membranes and conjunctivae reported for a beta blocker (pralidolol) have not been associated with propranolol.

DOSEAGE AND ADMINISTRATION. Inderal LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from Inderal Tablets to Inderal LA Capsules, care should be taken to assure that the desired therapeutic effect is maintained. Inderal LA should not be considered a simple mg-for-mg substitute for Inderal. Inderal LA has different kinetics and produces lower blood levels. Retitration may be necessary, especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION — Dosage must be individualized. The usual initial dosage is 80 mg Inderal LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood-pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily in some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS — Dosage must be individualized. Starting with 80 mg Inderal LA once daily, dosage should be gradually increased at three to seven-day intervals until optimal response is obtained. Although individual patients may respond at any dosage level, the average optimal dosage appears to be 160 mg once daily. In angina pectoris, the value and safety of dosage exceeding 320 mg per day have not been established.

Discontinuation of therapy should be gradual over a period of a few weeks (see WARNINGS).

MIGRAINE — Dosage must be individualized. The initial oral dose is 80 mg Inderal LA once daily. The usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimal migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximal dose, Inderal LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTROPHIC SUBAORTIC STENOSIS — 80-160 mg Inderal LA once daily. **PEDIATRIC DOSAGE —** At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

*The appearance of these capsules is a registered trademark of Ayerst Laboratories.

REFERENCES:

1. Inderal LA National Compliance Evaluation Program. Data on file, Ayerst Laboratories.
2. Ravid M, Lang R, Jutrin I. The relative antihypertensive potency of propranolol, oxprenolol, atenolol, and metoprolol given once daily. *Arch Intern Med* 1985; 145:1321-1323.

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Percutaneous Balloon Valvuloplasty of Calcific Aortic Stenosis

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Percutaneous balloon valvuloplasty has been reported effective in the treatment of pulmonary stenosis,^{1,2} mitral stenosis,³⁻⁵ aortic coarctation,⁶ and congenital aortic stenosis.⁷ Percutaneous transluminal coronary angioplasty is now firmly established as an effective treatment of coronary and peripheral artery stenoses. Several recent studies have described successful percutaneous balloon valvuloplasty in symptomatic patients with severe calcific aortic stenosis who were deemed poor surgical candidates or who refused surgical intervention.⁸⁻¹¹ These encouraging early reports suggest that percutaneous balloon valvuloplasty may be a viable alternative to aortic valve replacement in selected patients with critical calcific aortic stenosis.

This report outlines our initial experience with this technique. Each patient was considered at high surgical risk due to advanced age or other underlying medical conditions. Table 1 outlines the baseline demographic and relevant angiographic data in each patient. Procedures and results follow after the four case descriptions.

Case 1

A 72-year-old woman was transferred from an outside community hospital for evaluation of newly diagnosed aortic stenosis associated with bradycardia. The patient had a long-standing history of asthmatic bronchitis and significant essential hypertension. These conditions had been chronically treated with hydralazine, oral steroids, and methylxanthines. In addition, the patient had a history of mild renal insufficiency and a two-year history of progressive deterioration in her mental status deemed secondary to multi-infarct dementia.

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Table 1

Baseline demographic and angiographic parameters prior to valvuloplasty.

Patient	Age (Yrs)	Sex	Symptoms	Coronary Anatomy	AI	Other Valvular Disease
1	72	F	CHF	Insignif.	1+	MS
2	85	M	CHF, Syncope	1 VD	1+	None
3	89	F	CHF, Angina	3 VD, CABG	1+	MR
4	65	M	CHF	2 VD	1+	MR

CHF: Congestive heart failure; Insignif.: Insignificant coronary artery disease; 1-3VD: One, two, or three vessel coronary; CABG: Prior coronary artery bypass surgery; AI: Aortic insufficiency; MS: Mitral stenosis; MR: Mitral regurgitation.

In October 1986, she complained of increased weakness and fatigue, particularly on exertion, that increased over the next three to four weeks. She was hospitalized by her local physician who noted a cardiac murmur consistent with aortic stenosis and significant bradycardia. Because it was difficult to delineate whether the new onset of malaise, fatigue, and dyspnea on exertion were secondary to her chronic pulmonary disease or due to significant aortic stenosis, she was transferred for cardiac evaluation.

Physical examination was remarkable for jugular venous pulsations which revealed intermittent canon A-waves without significant jugular venous distention. Mild hepatojugular reflux was present. Carotid exam demonstrated a relatively normal upstroke and bilateral bruits. Cardiac exam revealed a palpable pulmonary outflow and a systolic thrill along the second left intercostal margin. The apex was readily palpable and slightly displaced laterally. On auscultation a grade IV/VI systolic ejection murmur was appreciated and a grade I/VI murmur consistent with aortic insufficiency.

A grade II/VI mitral insufficiency murmur was auscultated at the apex.

The chest x-ray revealed mild cardiomegaly, a markedly tortuous aorta, and evidence of mitral anular, aortic valvular and coronary calcification. The patient underwent a two-dimensional echocardiogram which showed evidence of left ventricular hypertrophy, normal left ventricular function, marked anular calcification, and suspected invasion of the mitral valve by calcium. The aortic valve was immobile and markedly thickened. The aortic root was mildly dilated. An 85 mmHg peak aortic valve gradient was estimated by Doppler along with mild aortic and mitral insufficiency, and evidence suggestive of mitral stenosis.

After careful consultation with the attending physicians regarding her risks of surgical intervention for aortic valve and, potentially, mitral valve replacement, it was decided that she was not a surgical candidate due to her age, dementia, essential hypertension, and chronic asthma. As an alternative, it was suggested that the patient undergo aortic valvuloplasty, which was undertaken with the patient's and family's informed consent.

Case 2

An 85-year-old man first had an aortic murmur diagnosed 30 years ago. During the summer of 1986, the patient had two episodes of exertional syncope. That November he developed increasing dyspnea on exertion as well as fatigue and dependent edema, including one episode of presyncope associated with dyspnea. A chest radiograph performed at a local hospital demonstrated findings consistent with congestive heart failure and left ventricular enlargement. Subsequently he was referred for further evaluation.

Physical examination was remarkable for jugular venous distention, delayed carotid upstroke, bibasilar rales, grade III/VI late peaking systolic murmur at the base radiating to the carotids and apex, an absent A2, and 2+ pitting edema below the knee. The electrocardiogram demonstrated atrial fibrillation with a moderate ventricular response and left ventricular hypertrophy with repolarization changes. The echocardiogram demonstrated normal left ventricular function, left ventricular hypertrophy, and a thickened immobile aortic valve. A Doppler examination revealed a 64 mmHg peak systolic aortic gradient and mild aortic insufficiency.

A cardiac catheterization was performed, which confirmed the diagnosis of severe degenerative calcific aortic stenosis (table 1). Due to his advanced age, the patient was considered at high surgical risk for aortic valve replacement. Aortic valvuloplasty was offered as an alternative.

Case 3

A 79-year-old woman had aortic stenosis diagnosed on routine exam at age 50. Due to progressive angina, she under-

went coronary artery bypass surgery in September 1982, with a single vein graft placed to the distal right coronary artery and a sequential graft to the left anterior descending, anterolateral, and obtuse marginal arteries. Her aortic stenosis was considered moderate at that time. A VVI pacemaker was implanted in 1981 for symptomatic bradyarrhythmias. Within the last six months, she developed progressive New York Heart Association functional class III angina and functional class III congestive heart failure. A recent diagnostic cardiac catheterization performed at another hospital demonstrated three-vessel coronary artery disease, widely patent grafts, and severe calcific aortic stenosis. Because of the patient's age and prior surgery, the patient was referred for further evaluation and possible catheter balloon valvuloplasty.

Physical examination on admission was remarkable for delayed carotid upstroke and bilateral carotid bruits. A grade III/VI late peaking systolic murmur at the aortic area, radiating to the neck, and markedly diminished A2 were auscultated. The electrocardiogram revealed 100% ventricular pacing. Cardiomegaly, predominantly left-sided, with congestive heart failure and interstitial edema were present on chest radiograph. Two-dimensional echocardiogram revealed aortic valve disease with severe aortic stenosis and a hypocontractile left ventricle. Doppler echocardiogram predicted a 64 mmHg peak gradient, a calculated mean gradient of 43 mmHg, and aortic valve area of 0.6 cm², mild mitral regurgitation, mild aortic insufficiency, and mild tricuspid regurgitation.

Case 4

A 65-year-old man had a history of a heart murmur dating back to World War II. In 1973 he was documented to have a myocardial infarction, and in 1983 he underwent permanent transvenous DDD pacemaker placement for complete heart block. Within the past several years he has had increasing symptoms of congestive heart failure, including progressive dyspnea on exertion, shortness of breath, and orthopnea. A catheterization two years prior revealed two vessel coronary artery disease with a totally occluded right coronary artery and a 75% stenosis in the proximal left anterior descending artery. Calcific aortic stenosis was noted with a calculated valve area of 0.5 cm², left ventricular ejection fraction of 21%, and 3+ mitral regurgitation. Considered an extremely high risk surgical candidate, he was referred for aortic valvuloplasty.

Physical examination was remarkable for slow carotid upstroke and small pulse amplitude. Jugular venous pressure was markedly increased. Bibasilar rales and both a left and a right ventricular heave were present. There was an aortic midsystolic murmur which transmitted faintly to the carotids, an S3, and no A2 present. Extremities revealed 2+ edema bilaterally. Electrocardiogram was AV sequentially paced. Chest radiograph showed interstitial edema and

marked cardiomegaly. The echocardiogram demonstrated a severely dilated and hypocontractile left ventricle with thickened and immobile aortic valve. The Doppler estimated a 56 mmHg peak systolic gradient, mild aortic insufficiency, and mild tricuspid insufficiency.

Catheterization Procedure

Each patient was premedicated with diphenhydramine HCL prior to the procedure, then with 3,000-6,000 units of intravenous Heparin after venous and arterial accesses were achieved. Right heart catheterization was performed via the left femoral vein with a #7F balloon tip flotation catheter (Critikon®). A #7F pigtail catheter was inserted through the left femoral artery and advanced to the descending aorta. Measurements were made of pulmonary artery, pulmonary capillary wedge, and aortic pressures. Oxygen consumption was measured with a metabolic cart (Beckman Sensormedics) as simultaneous aortic and pulmonary artery oxygen saturation and contents were obtained. Cardiac outputs were calculated by the Fick method in three patients and by thermodilution in one patient both before and after valvuloplasty.

Left heart catheterization was performed via the right femoral artery. A #7F right coronary catheter was placed through a #8F sheath and 175 cm, 0.038 inch straight-tipped guide wire was used to cross the aortic valve retrograde. After entrance into the left ventricle, a #7F Pigtail Millar® (two patients) or #7F pigtail catheter (two patients) was exchanged over a 260 cm J tipped guide-wire. Simultaneous left ventricular, supra-aortic and femoral artery pressures were recorded. Aortic valve area was calculated using the Gorlin formula, and peak-to-peak, mean, and peak instantaneous gradient were measured. Computerized digital left ventriculography and ascending root aortography were performed prior to and immediately after valvuloplasty.

Aortic Valvuloplasty Procedure

The pigtail catheter was removed over a 260 cm guide wire, and in patients two, three and four a #14F percutaneous sheath (Universal Medical Instrument Group) was placed in the right femoral artery, replacing the #8F sheath. Placement of a larger sheath permitted insertion of the valvuloplasty balloon and allowed postvalvuloplasty catheter exchanges to be accomplished without significant bleeding. The #9F 20 mm valvuloplasty balloon (Mansfield Inc.) was positioned across the aortic valve utilizing radiopaque markers on the catheter. Three inflations were made with a mixture of saline and contrast medium by hand injection. In all four patients a waist in the balloon was seen to appear at the level of aortic valve and to disappear during further balloon inflation (figure 1). All three balloon inflations in each patient lasted 10-20 seconds and were viewed by either fluoroscopy or two-dimensional echocardiography.

The simultaneous electrocardiogram and aortic pressure were recorded during all inflations. Following the final dilatation, repeat pulmonary capillary wedge, aortic, and left ventricular pressures were obtained. Oxygen consumption, pulmonary artery and aortic oxygen contents and saturations were also measured, and repeat cardiac output and aortic valve area were recalculated.

Results

All four patients demonstrated successful improvement in hemodynamics following percutaneous aortic valvuloplasty, as evidenced by an immediate reduction in mean aortic gradient and peak left ventricular to peak aortic pressure, with a concomitant increase in aortic valve area (table 2, next page). For the group as a whole, mean aortic gradient and peak aortic to peak left ventricular pressure fell by a mean of 30% and 32%, respectively; aortic valve area rose by 50%. A representative example of the improvement in

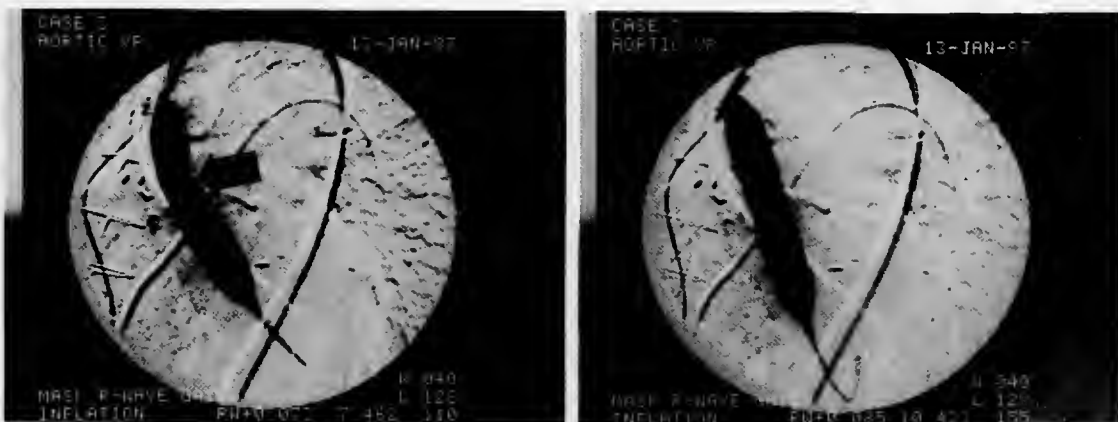


Figure 1. 20 mm diameter balloon filled with mixture of contrast and saline positioned across the aortic valve. The waist (arrow) is seen to disappear with full inflation (right).

Table 2

Hemodynamics, ventriculography, and congestive heart failure symptomatology before and after aortic valvuloplasty.

Patient	LV Peak Sys. Press. (mmHg)		Peak Ao Pressure (mmHg)		LV/Ao Peak-to-Peak (mmHg)		LV/Ao Mean Gradient (mmHg)		AVA (cm ²)		LVEF (%)		Mean PA (mmHg)		PCWP (mmHg)		C.O. L/min		CHF FC	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1	290	223	235	195	55	28	66	40	0.6	0.8	56	66	33	26	21	21	4.1	4.0	II	II
2	199	213	165	185	34	28	44	31	0.8	1.3	72	68	28	40	20	25	5.0	5.3	III	II
3	183	180	130	135	53	45	39	34	0.6	0.8	50	55	26	17	11	11	3.3	5.4	III	II
4	118	115	93	93	33	21	21	16	0.4	0.6	13	16	52	42	56	42	2.1	2.3	IV	II
Mean	197	183	156	152	44	30	43	30	0.6	0.9	48	51	35	31	29	25	3.6	4.3		
±SD	±71	±49	±61	±47	±12	±10	±19	±10	±0.2	±0.3	±25	±24	±12	±12	±18	±13	±1.2	±1.4		

LV peak sys. press.: Left ventricular peak systolic pressure; Peak Ao pressure: Peak aortic pressure; LV/Ao: Left ventricular/aortic; AVA: aortic valve area; LVEF: Left ventricular ejection fraction; Mean PA: Mean pulmonary artery pressure; PCWP: Mean pulmonary capillary wedge pressure; C.O.: Cardiac output; CHF FC: New York Heart Association functional class — congestive heart failure.

aortic peak-to-peak and mean gradient is shown in figure 2.

Mean pulmonary artery pressure and pulmonary capillary wedge pressure decreased in three of four patients, and cardiac output increased in three of four patients (table 2). Left ventriculography demonstrated an improvement in ejection fraction in all patients with a depressed left ventricular ejection fraction at baseline (table 2). In patient four, who had 3+ mitral regurgitation prior to valvuloplasty, mitral regurgitation was noted to be only 1+ after aortic valvuloplasty (figure 3). Ascending thoracic aortograms demonstrated no change in the degree of aortic insufficiency in any patient after aortic valvuloplasty.

In all patients, balloon inflation across the aortic valve of between 10 and 20 seconds was well tolerated. There were no symptomatic complaints during inflation, nor did aortic systolic pressure fall below 60 mmHg during the procedure. The serial aortic pressure for patient one is shown in figure 4 (facing page). Although catheter-induced ventricular premature contractions and non-sustained ventricular tachycardia were frequent, there were no episodes of

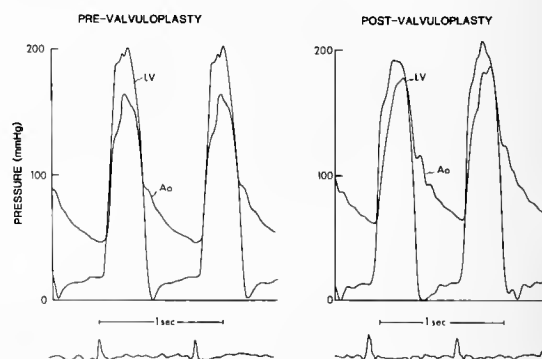


Figure 2. Simultaneous aortic (Ao) and left ventricular (LV) tracing before (left) and after (right) percutaneous aortic valvuloplasty in patient two. The peak-to-peak and mean aortic gradient have been significantly improved.

sustained ventricular tachycardia or ventricular fibrillation.

Patients two, three and four noted an improvement in symptoms of angina and dyspnea on exertion, and all pa-

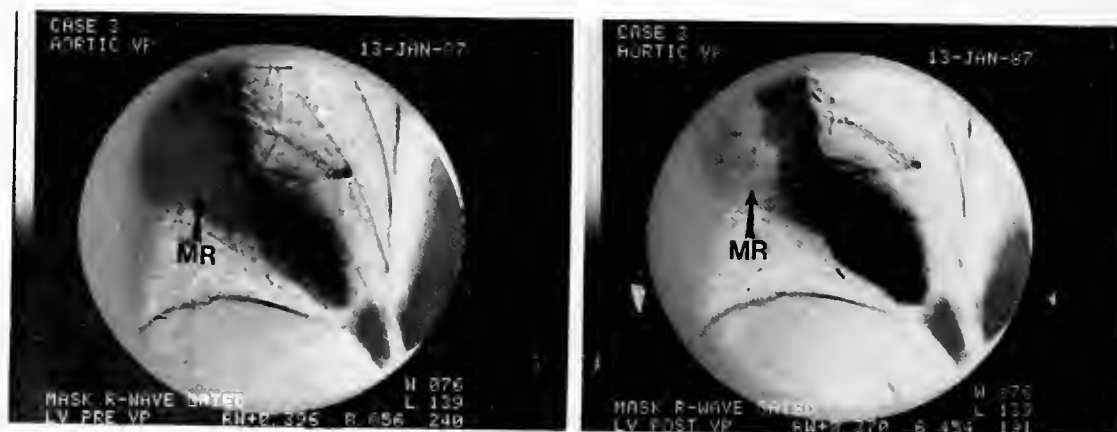


Figure 3. Left ventriculogram of patient four. Severe mitral regurgitation (MR) (left) is reduced to moderate mitral regurgitation following successful aortic valvuloplasty (right).

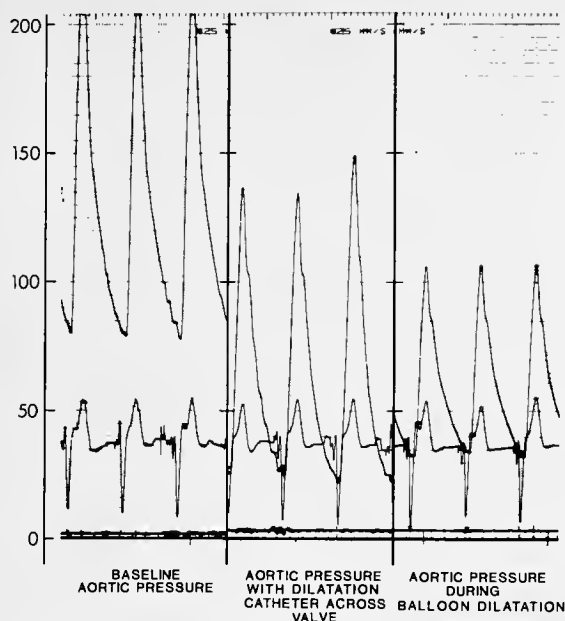


Figure 4. Aortic pressure and ECG recording in patient one at baseline, with catheter across stenotic aortic valve, and during balloon inflation. The placement of both catheter and balloon inflation were associated with a decrease in systolic aortic pressure from 210 mmHg to 105 mmHg.

tients were subsequently discharged ambulatory within ten days after the procedure. Due to dementia in patient one, symptom history was considered unreliable. In patient three, who had New York Heart Association functional class III angina prior to the procedure, improvement to New York Heart Association functional class II occurred during the hospitalization. In patients two, three and four, who presented with New York Heart Association functional class III, III, and IV congestive heart failure respectively, symptoms improved to functional class II.

After aortic valvuloplasty, the hospital course of patient one was complicated by a mild rise in total serum creatinine phosphokinase and MB fraction, suggestive of myocardial injury. However, her electrocardiogram remained unchanged and repeat radionuclide angiography revealed the left ventricular ejection fraction had risen to 85%. Additionally, her course was complicated by urosepsis and new unilateral weakness which resolved prior to discharge. An enhanced and non-enhanced CT scan of the head demonstrated multiple infarctions with no new areas of infarction. Two patients had significant blood loss requiring transfusion.

Discussion

Critical aortic stenosis presents a difficult management problem when the patient suffers from additional comorbid diseases that make aortic valve surgery a prohibitively high

risk intervention. The natural history of acquired significant aortic stenosis with the three cardinal symptoms of congestive heart failure, angina or syncope portend an extremely poor prognosis, with average survival less than five years.¹² In several recent reports, percutaneous aortic balloon valvuloplasty has been demonstrated to be a possible alternative to aortic valve replacement in patients with degenerative calcific aortic stenosis.⁸⁻¹¹ One multicenter study from France reported 158 patients with severe aortic stenosis in whom surgery was either relatively contraindicated or refused.¹¹ In most patients, significant improvement in hemodynamics was achieved with an acceptably low risk of complications. The mechanism of successful dilatation appears to be due to separation of fused commissures, fracture of calcified leaflets, and/or stretching of the valve cusps.⁹

This report further demonstrates the feasibility, safety, and palliative success of percutaneous aortic valvuloplasty in four patients where surgery had been excluded as a potential intervention. Hemodynamic improvement was documented by all catheterization parameters of aortic valve and left ventricular systolic function, including the aortic valve area, mean aortic gradient, and peak left ventricular to peak aortic pressure. This was accomplished without any detectable increase in aortic insufficiency. Each patient with depressed left ventricular ejection fraction had improvement in systolic performance following the procedure. Additionally, a rise in cardiac output was demonstrated.

In three patients, in whom a reliable history was obtainable, symptoms of angina, dyspnea, and shortness of breath were markedly improved during the hospitalization. While one patient did incur an increase in myocardial enzymes after the valvuloplasty, the electrocardiogram and follow up radionuclide angiogram as well as the clinical course were unaffected. It is possible that either emboli or coronary underperfusion during aortic balloon inflation contributed to this increase in cardiac enzymes.

Cerebral embolization is a potential concern in the performance of percutaneous aortic valvuloplasty. Cribier et al¹¹ noted one episode in 158 patients. McKay et al¹⁰ noted no clinically detectable episodes of cerebral embolization in a series of 49 patients in this country. While our patient one developed transient unilateral weakness on the day of the procedure, it is unclear whether this was related to the valvuloplasty. Computerized tomography could not conclusively demonstrate a new area of cerebral infarction. Further investigation is needed before conclusions regarding the risk of cerebral embolization can be substantiated. At this time it appears to be a minor risk.

The initial excellent results, especially the symptomatic improvement evident early after the procedure, suggest that catheter aortic balloon valvuloplasty is a reasonable and safe alternative to aortic valve replacement in the elderly patient, in those patients in whom surgery is an exceptionally high risk procedure or in those patients who refuse surgery for any reason. The procedure appears to be equally promising in the treatment of mitral stenosis as well. This exciting

new method offers hope for a palliative approach to stenotic valve disease in many patients in whom age, comorbid disease or other factors make valve replacement untenable. As the technique continues to evolve, the indications for balloon valvuloplasty procedures will likely expand. ■

Addendum

Since submission of this manuscript, we have successfully performed aortic valvuloplasty in eight additional patients, with no complications.

Acknowledgment

The authors wish to thank Cathey McCorkle for preparation of the manuscript, and Dr. Doug Packer, Dr. Frank Camp, Dr. Jack Taylor and Dr. William Eakins for referral of the patients reported here.

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Resolution of Appreciation

Whereas, Page Hudson, M.D., has recently embarked upon a new academic career, we the members of the North Carolina Society of Pathologists offer this resolution of appreciation.

Doctor Hudson has played the major role in the inception, nurture and growth of the office of Medical Examiner for the State of North Carolina. His academic background, drive, determination and commitment to excellence have brought that office to national prominence and made it a model for other states to follow.

Therefore, be it resolved, that Doctor Hudson be notified that the members of the Society appreciate his efforts in advancing the practice of Forensic Pathology in North Carolina, and that they all are pleased to know that he has elected to remain active in the teaching and the practice of Pathology in our state so that they will continue to enjoy his wit and good fellowship for many years to come.

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President

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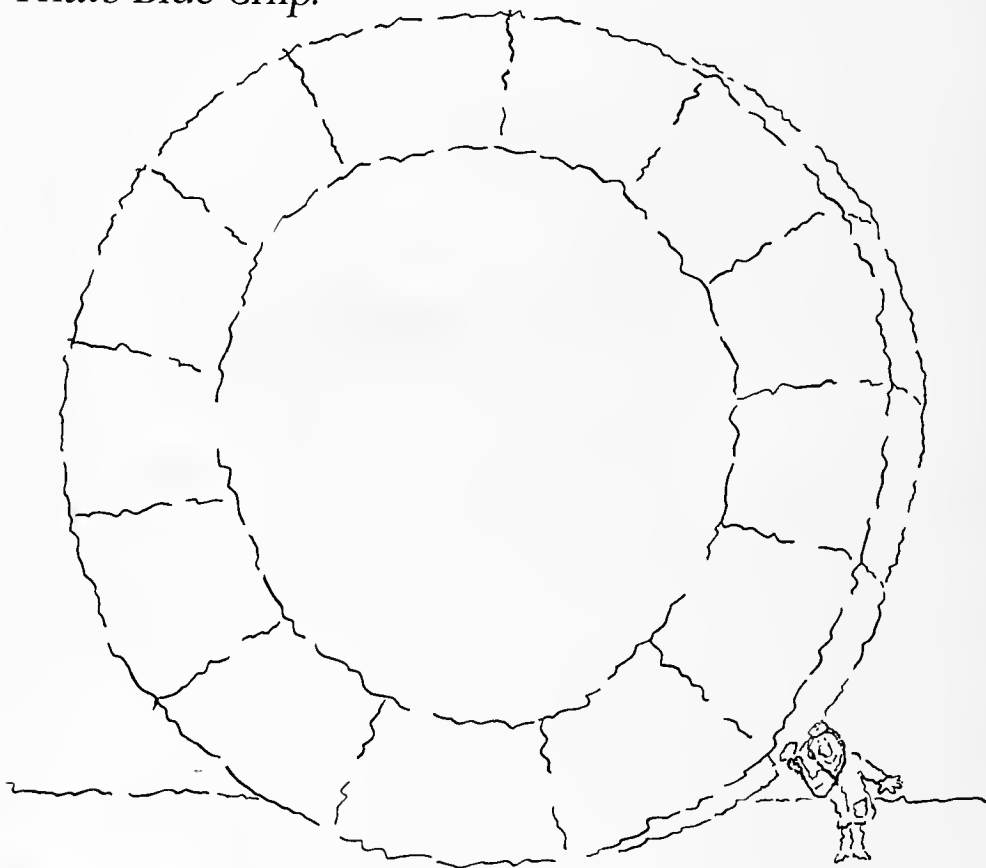
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CHANNEL
BLOCKER...**

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(verapamil HCl/Knoll)

240 mg scored, sustained-release tablets



JAMES B.
38, black male, heavy smoker. Prescribed a diuretic by another physician last year for hypertension.

YOUR CONCERNS
Presents with "smoker's cough." Workup reveals a BP of 150/107.

A LOGICAL CHOICE FOR CONTROL OF HIS BP
ISOPTIN[®] (verapamil HCl/Knoll) because...

- Black hypertensives often have low plasma renin activity and generally do not respond favorably to beta blockers.
- Beta blockers may increase the likelihood of bronchospasm.

ALICE W.
65, diabetic, overweight. Her BP has elevated to 190/98.

YOUR CONCERNS
She's on daily insulin.

A LOGICAL CHOICE FOR CONTROL OF HER BP
ISOPTIN[®] (verapamil HCl/Knoll) because...

- Unlike most beta blockers and diuretics, ISOPTIN has no adverse effects on serum glucose levels.
- Unlike most beta blockers, ISOPTIN does not mask the symptoms of hypoglycemia.



THOMAS G.
70, asthmatic. In the past, BP adequately controlled with 25 mg hydrochlorothiazide daily.

YOUR CONCERNS
Today patient presents with symptoms of gout. Workup reveals high uric acid level, low serum potassium, and BP elevated to 180/98.

A LOGICAL CHOICE FOR CONTROL OF HIS BP
ISOPTIN[®] (verapamil HCl/Knoll) because...

- Unlike diuretics, ISOPTIN will not decrease serum potassium levels or elevate uric acid levels.
- Unlike beta blockers, ISOPTIN can be used safely in asthma and COPD patients.

JOHN K.
42, Annual physical uncovered diastolic BP of 102... confirmed on three successive office visits. Unresponsive to nonpharmacologic intervention.

YOUR CONCERNS
Salesman, spends many hours of his working day in car... total cholesterol level 300, HDL 35.

A LOGICAL CHOICE FOR CONTROL OF HIS BP
ISOPTIN[®] (verapamil HCl/Knoll) because...

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Brief Summary

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CONTRAINDICATIONS: 1) Severe left ventricular dysfunction (see WARNINGS). 2) Hypotension (less than 90 mmHg systolic pressure) or cardiogenic shock. 3) Sick sinus syndrome or 2nd or 3rd degree AV block (except in patients with a functioning artificial ventricular pacemaker).

WARNINGS: **Heart Failure:** ISOPTIN should be avoided in patients with severe left ventricular dysfunction (see DRUG INTERACTIONS). Patients with milder ventricular dysfunction should, if possible, be controlled before verapamil treatment. **Hypotension:** ISOPTIN (verapamil HCl) may produce occasional symptomatic hypotension. **Elevated Liver Enzymes:** Elevations of transaminases with and without concomitant elevations in alkaline phosphatase and bilirubin have been reported. Periodic monitoring of liver function in patients receiving verapamil is therefore prudent. **Accessory Bypass Tract (Wolff-Parkinson-White):** Patients with paroxysmal and/or chronic atrial flutter or atrial fibrillation and a coexisting accessory AV pathway have developed increased antegrade conduction across the accessory pathway producing a very rapid ventricular response or ventricular fibrillation after receiving intravenous verapamil. While this has not been reported with oral verapamil, it should be considered a potential risk. Treatment is usually 0.5-1.0 mg/kg intravenous. **Atrioventricular Block:** The effect of verapamil on AV conduction and the SA node may cause asymptomatic 1st degree AV block and transient bradycardia. Higher degrees of AV block, while infrequent (0.8%), may require a reduction in dosage or, in rare instances, discontinuation of verapamil HCl. Patients with Hypertrophic Cardiomyopathy (HCS): Although verapamil has been used in the therapy of patients with HCS, severe cardiovascular decompensation and death have been noted in this patient population.

PRECAUTIONS: **Impaired Hepatic or Renal Function:** Verapamil is highly metabolized by the liver with about 70% of an administered dose excreted in the urine. In patients with impaired hepatic or renal function verapamil should be administered cautiously and the patients monitored for abnormal prolongation of the PR interval or other signs of excessive pharmacological effects (see OVERDOSAGE).

Drug Interactions: **Beta Blockers:** Concomitant use of ISOPTIN and oral beta-adrenergic blocking agents may be beneficial in certain patients with chronic stable angina or hypertension, but available information is not sufficient to predict with confidence the effects of concurrent treatment in patients with left ventricular dysfunction or cardiac conduction abnormalities. **Digitalis:** Clinical use of verapamil in digitalized patients has shown the combination to be well tolerated if digoxin doses are properly adjusted. However, chronic verapamil treatment increases serum digoxin levels by 50 to 75% during the first week of therapy and this can result in digitalis toxicity. Upon discontinuation of ISOPTIN (verapamil HCl), the patient should be reassessed to avoid underdigitalization. **Antihypertensive Agents:** Verapamil administered concomitantly with oral antihypertensive agents (e.g., vasodilators, angiotensin-converting enzyme inhibitors, diuretics, beta blockers, prazosin) will usually have an additive effect on lowering blood pressure. Patients receiving these combinations should be appropriately monitored. **Disopyramide:** Disopyramide should not be administered within 48 hours before or 24 hours after verapamil administration. **Quinidine:** In patients with hypertrophic cardiomyopathy (HCS), concomitant use of verapamil and quinidine resulted in significant hypotension. There has been a report of increased quinidine levels during verapamil therapy. **Nitrates:** The pharmacologic profile of verapamil and nitrates as well as clinical experience suggest beneficial interactions. **Cimetidine:** Two clinical trials have shown a lack of significant verapamil interaction with cimetidine. A third study showed cimetidine reduced verapamil clearance and increased elimination to 1/2. **Anesthetic Agents:** Verapamil may potentiate the activity of neuromuscular blocking agents and inhalation anesthetics. **Carbamazepine:** Verapamil may increase carbamazepine concentrations during combined therapy. **Rifampin:** Therapy with rifampin may markedly reduce oral verapamil bioavailability. **Lithium:** Verapamil may lower lithium levels in patient on chronic oral lithium therapy. **Carcinogenesis, Mutagenesis, Impairment of Fertility:** There was no evidence of a carcinogenic potential of verapamil administered to rats for two years. Verapamil was not mutagenic in the Ames test. Studies in female rats did not show impaired fertility. Effects on male fertility have not been determined. **Pregnancy (Category C):** There are no adequate and well-controlled studies in pregnant women. ISOPTIN crosses the placental barrier and can be detected in umbilical vein blood at delivery. This drug should be used during pregnancy, labor, and delivery, only if clearly needed. **Nursing Mothers:** ISOPTIN is excreted in human milk, therefore, nursing should be discontinued while verapamil is administered. **Pediatric Use:** Safety and efficacy of ISOPTIN in children below the age of 18 years have not been established.

ADVERSE REACTIONS: Constipation 8.4%, dizziness 3.5%, nausea 2.7%, hypotension 2.5%, edema 2.1%, headache 1.9%, CHF/pulmonary edema 1.8%, fatigue 1.7%, bradycardia 1.4%, 3° AV block 0.8%, flushing 0.1%, elevated liver enzymes (see WARNINGS). The following reactions, reported in less than 1.0% of patients, occurred under conditions (open trials, marketing experience) where a causal relationship is uncertain, they are mentioned to alert the physician to a possible relationship: angina pectoris, arthralgia and rash, AV block, blurred vision, cerebrovascular accident, chest pain, claudication, confusion, diarrhea, dry mouth, dyspnea, ecchymosis or bruising, equilibrium disorders, exanthema, gastrointestinal distress, gingival hyperplasia, gynecostasia, hair loss, hyperkeratosis, impotence, increased urination, insomnia, macules, muscle cramps, myocardial infarction, palpitations, paresthesia, psychotic symptoms, purpura (vasculitis), shakiness, somnolence, spotty menstruation, sweating, syncope, urticaria. **Treatment of Acute Cardiovascular Adverse Reactions:** Whenever severe hypotension or complete AV block occur following oral administration of verapamil, the appropriate emergency measures should be applied immediately, e.g., intravenously administered isoproterenol HCl, levalterenol bitartrate, atropine (all in the usual doses), or calcium gluconate (10% solution). If further support is necessary, inotropic agents (dopamine or dobutamine) may be administered. Actual treatment and dosage should depend on the severity and the clinical situation and the judgment and experience of the treating physician.

OVERDOSAGE: Treatment of overdosage should be supportive. Beta-adrenergic stimulation or parenteral administration of calcium solutions may increase calcium ion flux across the slow channel, and have been used effectively in treatment of deliberate overdosage with verapamil. Clinically significant hypotensive reactions or fixed high degree AV block should be treated with vasopressor agents or cardiac pacing, respectively. Asystole should be handled by the usual measures including cardiopulmonary resuscitation.

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3. I'm on the grapefruit diet.
4. I gave six months ago.
5. I just got back from Monaco.
6. The lines are thirteen blocks long.
7. My mother won't let me.
8. I didn't sign up.
9. I'm going out of town.
10. Asthma runs in my family.
11. I forgot to eat this morning.
12. I'm allergic to flowering magnolia.



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Through All Thy Veins Shall Run a Cold and Drowsy Humor

Nightshade Poisoning

Ronald B. Mack, M.D.

Many loyal readers of this column are aware that I have lived before. During the Renaissance, in Rome and Florence, I was the chief poisoner for the Borgias — actually one of the better jobs in my long history. During this interval I received a letter from a Friar Lawrence in Verona. The good cleric had a problem; he had a pair of "star-crossed" lovers who wanted to get married but their families were deadly enemies and the girl in this problem was to be married to someone else, not of her choosing. Now Friar Lawrence was also an alchemist and knew a lot about plants, herbs and so on but he needed a consult on what to give a young person who wanted to appear dead but not really die. He was hoping to find a drug to put this lady "out of it" for a few days. Thinking she was dead, her family would leave her in the family tomb and when she awoke her lover would spirit her out of town on a big Harley and they would live happily ever after.

After giving this matter much thought I recommended the *nightshade* plant and I instructed him to tell his prospective client that "no pulse shall keep his native progress, but surcease; no warmth, no breath, shall testify thou livest."¹ The rest is history, as they say; the lovers died by suicide and Juliet's father is suing me for not getting informed consent. By the way, Romeo, the stud in this tale, goes to an apothecary, buys some cheap poison to do himself in and succeeds. He went to a discount poisoner.

As a potential poison the nightshade plant still exists and in fact is a very commonly ingested substance even as we speak. In the 1985 Annual Report of the American Association of Poison Control Centers, in data representing 48% of the human poison exposures reported to poison centers, there were 1,984 exposures to this plant type, almost all in children under the age of six years.² Whereas the philodendron is by far the most commonly reported ingested flora, the nightshade plant has consistently remained in the top 10 most common plant exposures during the past few years.³

The designation "nightshade" can be very confusing to

those unfamiliar with the botanical literature, because there are several plants in the nightshade family,⁴ such as:

The Woody Nightshade (AKA the Climbing Nightshade or Bittersweet) — *Solanum dulcamara*.

The Deadly Nightshade (AKA the Black Nightshade) — *Solanum americanum* (U.S. variety) and *Solanum nigrum* (European variety).



Solanum dulcamara.
Reprinted from CR Bell. Plant variation and classification. Belmont CA, 1967. Drawings by Susan Carlton Smith.

The confusion in the literature generally surrounds the terms "bittersweet" and "nightshade." For example, the plant *Celastrus scandens*, which is weakly poisonous, is also called "bittersweet" or "climbing bittersweet." *Solanum dulcamara* is often referred to as "bittersweet" or "European bittersweet" but is commonly called the "nightshade," "deadly nightshade" or "climbing nightshade." Even more confusing, especially to me, is the common reference to *Atropa belladonna* as the "deadly nightshade." This latter plant is the only "nightshade" that does not contain solanine (*vide infra*). This epistle will only discuss the nightshades in the *solanum* genus and will leave the *Atropa belladonna* for another day.

Let me not fail to mention other members of the nightshade genus *Solanum* group⁵ with which you may or may not be familiar:

From the Department of Pediatrics, Bowman Gray School of Medicine, Wake Forest University, Winston-Salem 27103.

The Jerusalem Cherry — *S. pseudocapsicum*

The potato — *S. tuberosum*

The horse nettle — *S. carolinense*

The nightshade genus that we are discussing derives its scientific name from the Latin word for quieting — *solanem* — possibly because of its historical use as a sedative producing plant. This genus is quite large and has 1,700 separate species, most of which have never been evaluated from a toxicology viewpoint. The plants themselves are usually herbs (sometimes of the climbing variety) or shrubs; they are often spiny or hairy or have stinging hairs. Among the distinctive features of the nightshades are the star-shaped or bell-shaped flowers with fused petals. The berries can be black, orange, yellow or red, and are pea- to grape-sized with small seeds.

Although nightshades contain many potentially toxic substances such as steroidal alkaloids, saponins, esters and free parent alkalamines, the more common putative culprit in the typical nightshade ingestion is the glycosidal alkaloid, *solanine*. All parts of the plant, leaves included, are potentially poisonous, with the unripe fruits (the berries, of course) containing the highest concentrations. It has been alleged that the berries of the woody nightshade (*S. dulcamara*) and the deadly nightshade (*S. americanum* and *S. nigrum*) are especially toxic potentially. All parts of the white potato plant except the tubers contain serious amounts of solanine; and heavy concentrations may be present in green or "spoiled" tubers, usually under the skin and in the sprouts or "eyes."

If, like me, you have trouble identifying any flora that is unlabeled, seek the counsel of the nearest high school or college botany teacher or the manager of a successful plant and garden store. In the city streets where I grew up, flower tending and flower identification were not necessary requirements for "street sense," so my education in this area is remarkably deficient, unfortunately. "Street sense" can be embarrassing sometimes. In boot camp during World War II, while undergoing instruction in hand-to-hand combat prior to a possible invasion of the country that now produces my car, TV, VCR, compact disc player, etc., I asked the Drill Instructor if it was OK for me to use tire chains as a weapon.

Small amounts of the solanine group of plants are all that is necessary to produce adverse clinical features. Whereas solanine-plant ingestion does not have remarkable toxicity in adults, fatal poisoning due to this group of plants has been reported in children.^{2,6} Onset of illness following ingestion can vary from early to a delay of 12 to 24 hours before clinical toxicity occurs. The signs and symptoms of solanine intoxication appear to be related to the degree to which this toxic alkaloid is metabolized and absorbed.

As you might suspect, the toxicological features can be divided into *local* and *systemic*. The presence of solanine in the gastrointestinal tract produces local irritation as manifested by nausea, vomiting, diarrhea and abdominal pain.

These symptoms and signs are by far the most common ones seen with this poisoning. Solanine poisoning can easily be confused with a bacterial gastroenteritis, unless a good history is available. Accompanying this gastrointestinal insult there is an irritating, scratchy feeling in the pharynx and an elevated body temperature. If the toxin is absorbed, the abnormalities produced are primarily in the central nervous system (CNS), and you may see such bad signs and symptoms as drowsiness, dyspnea, muscular weakness, CNS depression with progression to respiratory failure, coma, shock and possible death. Bradycardia is a typical event in solanine poisoning. Paresthesias such as loss of sensation are also seen in severe cases. To reiterate, solanine has low toxicity for adults, but can be fatal to a child.

It is difficult, in perusing the literature, to determine how many berries it takes to poison a child. Some authors, even recently, allege that as few as two or three unripe berries can produce symptoms⁷ and that as few as ten berries are potentially fatal to a small child. In any event, it is practically never possible to exactly quantify the ingestion in most plant poisonings, especially in non-witnessed ingestions by preschool children.

The management of a patient with suspected or known solanine poisoning is quite non-specific and supportive: gastric emptying and charcoal administration, support of the cardiorespiratory systems, and maintenance of fluid balance. There is no antidote for this intoxication.

There is no question that Shakespeare knew about the many drugs available in his time, because he wrote about sleep-inducing drugs from such plants as poppy and mandragora (mandrake). At least some authorities speculate that Friar Lawrence slipped Juliet some nightshade to produce the sleep state she desired, telling her, "and in this borrowed likeness of shrunk death, thou shalt continue two and forty hours, and then awake as from a pleasant sleep."¹ Actually, as you know, she awoke and found her lover taking the Big Sleep. Now they are both dead and I'm being sued. I tell ya, I get no respect. ■

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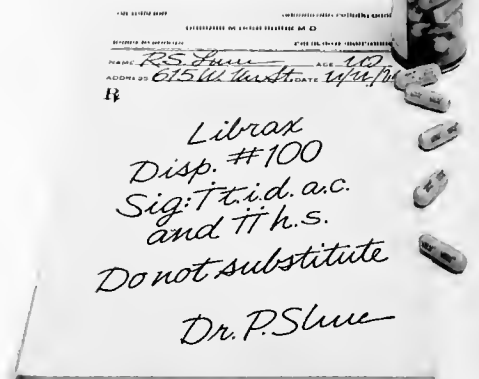


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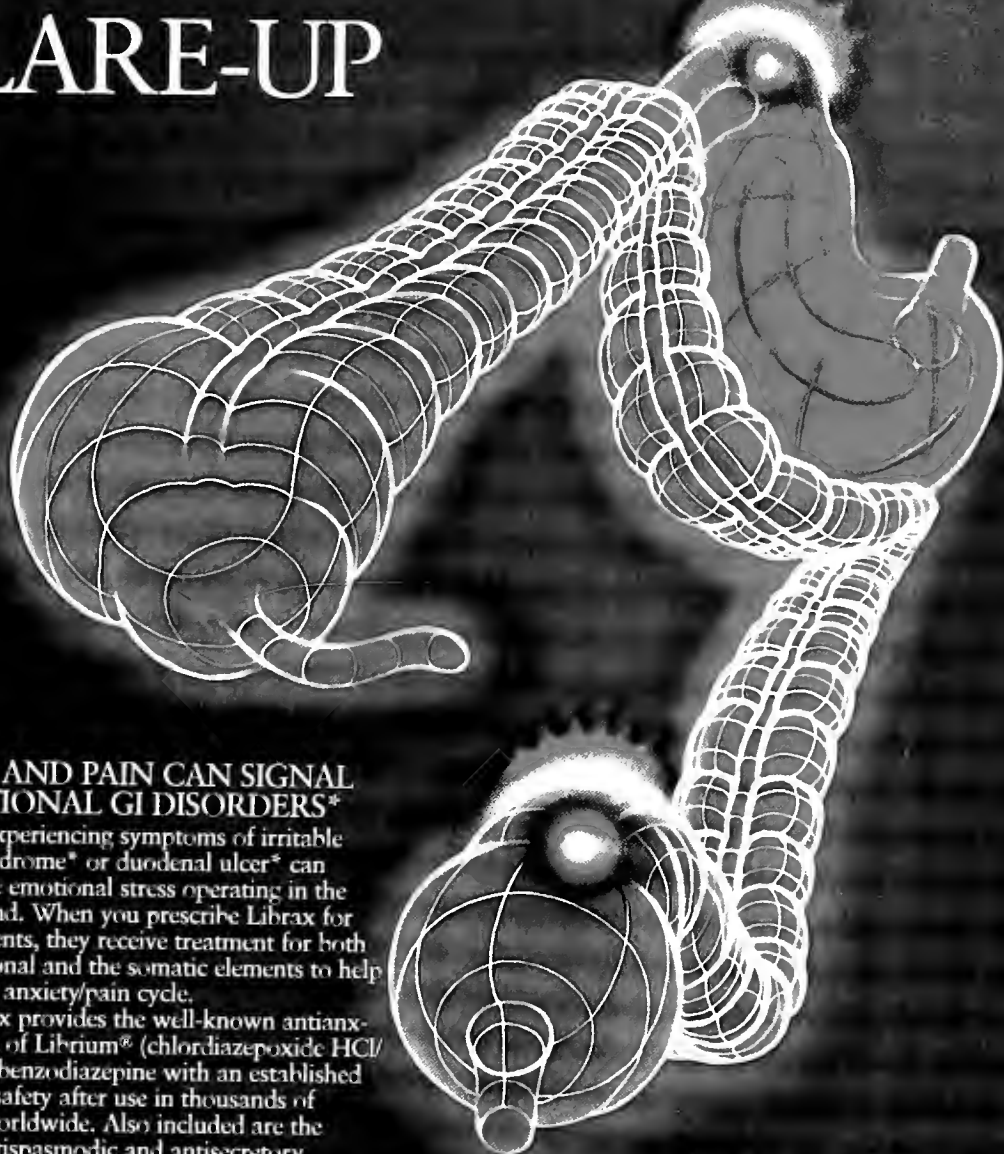
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NORTH CAROLINA MEDICAL JOURNAL

For Patients

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Teens and Sex

Confessions of an Imperiled Liberal

JOHN F. STEEGE, M.D.

A "conservative" is a "liberal" with a teenage daughter.

Adolescence is tough. When I was 16, my biggest concern was getting my curve ball over the plate. Sex was fantasy. If my young daughter were 16 today, she would be dealing with far weightier matters, according to a survey conducted for the Planned Parenthood Federation by Louis Harris and Associates, Inc. Following in the next pages, see the survey topics and highlights of the findings reprinted from the lengthy survey report published in 1986 by Harris and Planned Parenthood.

Harris polled 1,000 teenagers from across the country in September and October of 1986. The results indicate that if my daughter were 16:

Forty-six percent of her peers would have already had intercourse (not my daughter).

If her grades fell or her career goals became uncertain, she would be more likely to start having sex.

She would say that others feel pressured to have sex (73%), but would be less likely (28%) to admit feeling pressured herself.

If sexually active, she would be more likely to use birth control (60%-70%) because she is the daughter

of white college-educated parents; if she were black and the daughter of non-college-educated parents, she would be less likely (20-35%) to use contraception some or all of the time.

If she had talked with me about sex and contraception, she would be more likely to use contraception if sexually active (48% vs 26%).

Further, she and her peers would be likely to have some form of sex education in their schools (59%), but only some of the courses would be comprehensive (35%). A high level of knowledge about sexuality is associated with regular contraceptive use (45%) as compared to a low level of knowledge (15%). Despite these efforts, she and her friends would still have significant areas of ignorance: 35% would see the condom as unreliable, while many would feel that the birth control pill (23%) or the diaphragm (20%) can be obtained at the drug store without prescription; 12% would believe that the pill causes cancer and 11% would believe it causes infertility. Finally, 14% would hold the magical belief that pregnancy could not happen to them.

Okay, so far, so good. All I've got to do is keep the lines of communication open, encourage positive goals in life, and support her extra-curricular interests (can't somebody else take the carpool today?). But now she tells me that a lot of her friends think a birth control clinic

From the Division of Gynecology, Department of Obstetrics and Gynecology, Duke University Medical Center, Box 3263, Durham 27710.

should be located either in their school (12%) or conveniently near it (28%). A third of her friends feel that they would have trouble affording the \$5 to \$20 a month expense of contraception (would I really like to see this as a line item on her allowance budget?). Almost all (78%) of her friends (not my daughter) want their contraceptive care to be confidential. Despite my being a gynecologist, she and her friends (70%) see the pelvic examination as a major obstacle to acquiring contraception.

I'm nervous. What if I dig in my heels and say she shouldn't attend that sex education course? She's no less likely to begin sexual activity, but she is less likely to use contraception. If I choose to raise her as a fundamentalist Christian, she might be less likely to become sexually active (25% vs 50%), but if active would be less likely to use contraception (22% vs 35%).

Thankfully, I'm getting a lot of help. The American College of Obstetricians and Gynecologists (ACOG), led by past president Luella Klein, M.D., has waged an active campaign to reverse media restrictions on contraceptive

advertising. Condom ads have begun on TV in North Carolina. ACOG President Harry S. Jonas, M.D., has started the College on a project of developing sex education programs which will be ready shortly. The Adolescent Health Care Committee of the College has been examining sex education curricula and coordinating efforts with other educational groups. U.S. Surgeon General C. Everett Koop, M.D., reacting to the AIDS crisis, has become a supporter of sex education. A recent Gallup Poll reports that 78% of adult Americans support sex education before high school, and approximately half support it at the elementary school level.

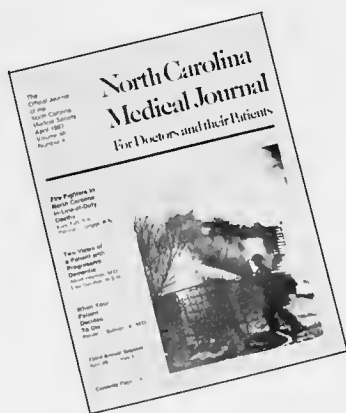
My daughter: I hope when the time comes she feels comfortable asking me. Then again, I hope she doesn't need to. I think I'll work on this editorial in the office instead of at home.

P.S. My son has not yet reached the age of genital awareness. I'll worry about him later. ■

- Editor's note: Dr. Steege teaches Human Sexuality to Duke University undergraduates and medical students. He directs the Biobehavioral Gynecology section of the division of Gynecology, including the Premenstrual Syndrome Clinic, Pelvic Pain Clinic, and Sex Therapy and Education Program.

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"American Teens Speak"

Report on a Survey

THE PLANNED PARENTHOOD FEDERATION OF AMERICA, INC.

The Planned Parenthood Federation of America, Inc., commissioned a poll of 1,000 teenagers in their homes by Louis Harris and Associates, Inc., and published the findings in a pamphlet entitled "American Teens Speak: Sex, Myths, TV, and Birth Control." Reprinted here are the topics covered and highlights of the findings.

What They Hoped To Find Out

The topics in the survey include:

The reasons why so many teenagers do not wait to have sexual intercourse.

The reasons why so many sexually active teenagers do not use birth control.

Arguments that teenagers think would influence their peers to delay sex.

Arguments and steps that teenagers think would influence their peers to use birth control.

Areas of knowledge and areas of ignorance or myth about sexuality.

Sources of information (and misinformation) about sexual topics.

The perceived realism of TV in dealing with sexual topics.

The content of sex education courses in the schools, as reported by the pupils who have actually taken them.

The extent of talks between parents and children on sex and birth control.

The resulting impact on teenagers' sexual behavior of knowledge, parental talks, and sex education courses.

The barriers that remain to increased use of birth control by teenagers.

Highlights of the Survey Findings

Teenage sex and use of birth control. The survey documents the scope of a national problem: many teenagers are sexually active, and yet many do not usually use birth control. High rates of teenage pregnancy are the inevitable result. And those results will fall heaviest, the survey shows, at those levels of society where teenagers and their parents have the least resources to cope with the problem.

1 *More than half of America's teenagers report having had sexual intercourse by their seventeenth year.* Of all U.S. teenagers age 12 through age 17, nearly three out of ten (28%) say they have had sexual intercourse. The proportion increases rapidly with age, rising from 4% of the 12-year-olds to 57% of the 17-year-olds.

2 *Sexual activity begins earlier among those teenagers who have the fewest resources, and who are thus the most vulnerable.* Teenagers whose parents are not college graduates, teenagers who have grades in school averaging C, D, or F, and black teenagers are all more likely to have had sexual intercourse.

3 *Teenagers say that social pressure is the chief reason why so many of their peers do not wait to have sexual intercourse until they are older.* Both boys as well as girls cite social pressure more frequently than other factors, but girls mention it (73%) more than do boys (50%). More girls (28%) than boys (21%) also say that they themselves have personally felt pressured by other teenagers to go farther with sex than they wanted to.

4 *Only one-third (33%) of those teenagers who have had intercourse say that they use contraceptives all the time.* Nearly as many (27%) say that they never use them. The rest say that they use contraceptives "sometimes" or "most of the time."

5 *Teenagers who have the fewest resources are the most likely to be at risk by not using contraceptives.* Among sexually active teenagers, those whose parents are not college graduates, those who live with only one parent, and black and Hispanic teenagers are all less likely to use contraceptives.

6 *Teenagers who have had intercourse say that "un-*

expected sex" — with no time to prepare — is the most frequent single reason why they and so many of their peers do not use birth control. Other categories of reasons cited by teenagers as a whole include: that many simply prefer not to use birth control (39%), that many do not know enough about contraceptives or can't get access to them (25%), that many are too afraid and embarrassed to get contraceptives or fearful that their parents will find out (24%), and that many believe they are safe without contraceptives, that pregnancy will not happen to them (15%).

7 Contraceptives are most likely to be used by those teenagers who can see they have a lot at stake and who stand to lose a lot by being involved in an unintended pregnancy. This includes those who can name some career they aspire to, those whose grades are in the A or B range, and those who are involved in sports or extracurricular activities. They have extra incentive to look ahead and to plan beyond the moment. They are more likely to have both the motive and the resources to overcome a cultural tradition that, while valuing spontaneity in human relationships, often discourages any combination of "planning" with "romance."

The impact of knowledge, talks with parents, and sex education at school. Education and information, the survey shows, have enormous impact on teenagers' sexual behavior. Therefore, a major priority for society in dealing with the problem of teenage pregnancy is to find ways of increasing the information that teenagers have at their disposal. This means encouraging more parents to talk openly and in detail with their own children about sexuality and contraception. It also means improving both the availability and the comprehensiveness of sex education in the schools.

1 Teenagers who have talked about sex, pregnancy, and contraception with their parents are more likely to use birth control all the time if they are sexually active. Of sexually active teenagers who have had no talk with their parents, only 26% use birth control all the time. This figure rises to 37% among those who have some kind of talk about sex with their parents, and to 43% among those whose talk included the subject of birth control.

2 Two-thirds of American teenagers (68%) have at some time talked to their parents about sex and how pregnancy is caused. But only one-half of those (33% of all teenagers) had talks that included the subject of birth control. Girls are more likely to have had discussions with their parents than are boys. Whites and blacks are more likely than Hispanic teenagers. And those whose parents are college graduates are more likely to have talked about sex with their parents, but they are no more

"Education and information . . . have enormous impact on teenagers' sexual behavior."

likely to have talked about birth control.

3 Teenagers who have had a comprehensive sex education course at school are more likely to use birth control all the time if they are sexually active. Of sexually active teenagers who have had no sex education course, only 25% say they use birth control all the time. That figure rises slightly to 30% among those who have had a formal sex education course which was not comprehensive. Of those who had a course which was comprehensive, 40% use contraceptives all the time.

4 A majority of American teenagers (59%) have had some kind of formal course or class on sex education at school. But only 35% of all teenagers have had a sex education course whose content could be called comprehensive. "Comprehensive" was defined as including at

least four out of the following six topics: biological facts of reproduction, coping with sexual development, different kinds of birth control, information about where to get contraceptives, information about preventing sexual abuse, and facts

about abortion.

5 Teenagers who have greater knowledge about sexuality — gained from whatever source — are also more likely to use contraceptives all the time if they are sexually active. Of sexually active teenagers who have a low level of knowledge about sexuality, only 16% use birth control all the time. That figure rises to 25% among those who have a medium level of knowledge. It rises greatly among those with a high level of knowledge; 45% of them use birth control all the time.

6 Many teenagers are confused or uncertain in their knowledge of basic facts about sexuality. And many of the teenagers who are most at risk of pregnancy turn out to have the least knowledge. For instance, only 40% of all teenagers know it is usually true that a girl is most likely to become pregnant about two weeks after her menstrual period begins; 59% give the wrong answer or are not sure. From this and six other such facts, a "sexuality knowledge index" was constructed to show which teenagers are most knowledgeable and which are confused or ignorant. Those whose economic status is low have less knowledge than do those with a higher economic status. And those with lower grades in school also have less knowledge. And black and Hispanic teenagers have less knowledge of these topics than whites.

Thus there is a vicious cycle at work that compounds social and economic disadvantage with disadvantages in dealing with the world of sexuality. Low sexual information — with a resulting greater risk of pregnancy — is simply one more way in which socially disadvantaged teenagers get left behind.

7 But it is possible to break into this cycle. For greater knowledge of sexuality is shown both by teenagers who have talked with their parents and by teenagers who have

had formal sex education in school. Parent-child communication would seem to be an under-utilized resource that has a large potential for improving the situation. Teenagers rank parents as first in importance out of eleven possible sources of information about sex and birth control. Yet, as we have seen, only one-third of all teenagers currently say they have actually discussed birth control with their parents. This potential, however, may never be fully realized. Forty-two percent of teenagers say they would be nervous or afraid to bring up the subject with their parents. And last year's [1985] Planned Parenthood Poll of adults across the U.S. showed that many parents themselves feel they need outside help in educating their children about sex and birth control.

8 *Sex education in the schools is the other way that society can break the cycle of low social status — low grades — low information about sexuality — low use of contraceptives — high risk of pregnancy.* Teenagers currently rank courses at school as third most important out of eleven possible sources of information about sex and birth control. Yet, as reported above, only 35% of all teenagers currently have had a comprehensive sex education course, indicating that here, too, there is a large potential for improving the situation.

9 *It is important that both parents and schools play a greater role, for the other two most important sources of teenagers' information are their own friends (second in importance out of eleven possible sources) and television and movies (fourth in importance out of eleven).* As for teenagers' friends, in many cases they are no more knowledgeable than they [respondents] are themselves. Regarding television's portrayal of sexual subjects, in this year's survey teenagers were asked the same questions about television that adults had been asked in last year's survey. The results show that teenagers have greater faith in the realism of television's portrayal of sexual subjects than adults do. For instance, 41% of teenagers think that television gives a realistic picture of pregnancy and the consequences of sex. Only 24% of adults think that.

Further steps that society can take. In addition to encouraging parent-child talks and sex education in the schools, society may also wish to intervene in additional ways, such as by an organized campaign for teenage pregnancy prevention [see the article that follows for information on one local project in North Carolina]. For such a campaign, the survey shows a number of the tools which can prove effective.

1 *In evaluating arguments for delaying sex, teenagers say that the danger of catching sexually transmitted diseases and the danger of a pregnancy ruining one's life are two messages that are most likely to influence their peers.* Sixty-five percent think that telling teenagers to

"Teenagers rank parents first in importance (for) information about sex and birth control."

worry more about catching diseases like AIDS and herpes would be likely to influence them to wait to have sexual intercourse. Sixty-two percent think that telling them how a pregnancy could ruin their life would be effective. While such arguments may prove useful in convincing some teenagers to delay sex, in some cases the delay may serve mainly to postpone an unintended pregnancy until a later age, rather than to prevent it altogether. Further steps are needed in pregnancy prevention.

2 *In evaluating steps to encourage the use of birth control, teenagers say that guaranteeing confidentiality, making birth control free, and making birth control easy to obtain are most likely to influence their peers.* Guaranteeing confidentiality in obtaining birth control ranked first (78%) out of eight steps that were evaluated. Making it free of cost ranked second (75%) and making it easy to obtain ranked third (70%) out of the eight steps.

3 *When teenagers are asked to compare various methods of birth control, they overwhelmingly prefer the pill and the condom. No other method ranks anywhere close.* Girls tend to prefer the pill (63%), while boys tend to prefer the condom (53%). They view these methods as effective, safe, easy to use (in the case of the pill), and easy to buy (in the case of the condom).

4 *There is unmet demand for the birth control pill.* When the methods of birth control preferred by teenagers are compared with the actual methods most frequently used, it is apparent that many more prefer the pill than actually use it. Sixty-three percent of girls would prefer the pill, but only 38% of sexually active girls actually use the pill. There is much less fall-off in the case of the condom. Fifty-three percent of boys prefer the condom, and 47% of sexually active boys actually use that method.

5 *One barrier to increased use of the birth control pill may be the pelvic examination that is usually required by physicians and clinics.* Sixty-nine percent of girls say that this requirement frightens many girls away. A similar proportion of agreement (70%) was registered by those girls who have actually used the pill and who, presumably, have themselves undergone a pelvic exam. Thus, firsthand experience with the pelvic exam does not remove the fear of it.

6 *For some teenagers another barrier to increased use of contraceptive methods in general is cost.* When informed that most methods of birth control cost between \$5.00 a month and \$20.00 a month, one-third of all teenagers (33%) say this is too much for them to pay. While only a minority of all teenagers cite cost, they include a disproportionate number of those who are most at risk: 35% of black teenagers and 40% of Hispanic teenagers.

7 *An additional barrier to increased use of birth control is misinformation about the effectiveness and side*

effects of various methods. For instance, 39% of teenagers think that condoms are ineffective in preventing pregnancy, or don't know. Seventeen percent think that withdrawal works well in preventing pregnancy. Of more than a dozen side effects of the pill mentioned by teenagers, those cited second and third most frequently were that it causes cancer (12%) and causes sterility (11%), neither of which is true.

8 *A further barrier to increased use of birth control is accessibility or perceived inaccessibility.* One way to increase accessibility would be to establish school-linked clinics where contraceptives could be obtained. Forty percent of teenagers endorse this idea. Somewhat more say that the clinic should be located close to the school (28%) rather than inside the school (12%), perhaps to ensure the confidentiality that they ranked as the number one step needed to increase use of birth control. Thirty-one percent of all teenagers think their own school needs such a clinic. These percentages are even higher among the groups for which access to contraception is most likely to be important. For instance, a majority of those who are sexually active favor the idea of school-linked clinics, as do a majority of black teenagers.

9 *If pregnancy prevention fails, then abortion remains as an option that teenagers want, on balance, to keep open as a possibility.* Like adult Americans, teenage Americans have mixed feelings on this subject, but on balance they favor the availability of abortion by a 47% to 40% ratio. The ambivalence that this reflects means that most teenagers do not look to abortion as the easy way out of an unwanted pregnancy or as any reason to neglect birth control in the first place. Pregnancy prevention remains the first priority.

10 *Finally, it would be very helpful to increase the number of teenagers who realize they have a lot at stake and a lot to lose by being involved in an unintended pregnancy.* The survey shows that most teenagers have high hopes for their careers and that teenagers overwhelmingly (94%) believe that they will succeed in life if they work hard. The survey also shows that those who objectively have the most to lose do use birth control more frequently. What is needed, then, is for more teenagers to understand that connection: how being involved in an unintended pregnancy can interfere with their hopes and dreams for success in their lives. ■

A Local Project To Reduce Teen Pregnancy

PAULINE FRAZIER

Assistant Executive Director, Durham YWCA

The Durham YWCA is spearheading a project that will use several creative approaches to this problem.

Children having children has become a major problem across the nation, including our own North Carolina. The incidence of pregnancy among adolescents has risen steadily in the past two decades. Unfortunately, the problem does not stop there. It results in an increase of school dropouts, teen suicide, deaths at birth, and other serious medical and psychosocial problems. The Durham Young Women's Christian

Association (YWCA) along with three other local organizations is undertaking a project that will work directly with teenagers to test methods for reducing the number of teen pregnancies.

The Problem Nationwide

Nationally, one in ten adolescent girls become pregnant each year; four out of ten will become pregnant once in their teens; two out of ten will give birth; one out of

From the Durham YWCA, 809 Proctor St., Durham 27707.

seven will have an abortion; and one in ten pregnant teens will commit suicide. Pregnancy is the reason most often cited by female teenagers for dropping out of school. Eight out of ten women who first become mothers at age 17 or younger never complete high school.

Compared to women who become pregnant in their 20s, teenage mothers are less likely to be in the labor force and more likely to be on welfare, in part because the many who drop out of school tend to be unskilled. While teenagers become pregnant in increasingly alarming numbers, cutbacks in the very service programs they are likely to need assure a larger generation destined for poverty.

The Problem in Durham

The situation in Durham County is a reflection of the national picture. The county now ranks fifth in teen pregnancy rate among the state's 100 counties.

In Durham, in 1984, 53 of the 5,490 girls between the ages of 10 and 14 reported pregnancies. They had 37 induced abortions and 16 live births. Eleven percent (711) of the 6,417 teenage girls between the ages of 15 and 19 became pregnant. They had 431 induced abortions, 276 live births, and 4 fetal deaths.¹

There was little or no reduction in maternal and child health (MCH) risk factors over 1983. The latest data reveal that among teens 15 to 19 years old, 13.6% of those delivering had low birth weight babies (5 lb 8 oz or less). This compares unfavorably with deliveries to those 15 to 44, in whom the low birth weight rate was 9.7%. Similarly, 15- to 19-year-old mothers had received late or no prenatal care in 43.6% of the cases, compared to only 17.7% for those 15 to 55 years of age. Fully 93.2% of the mothers aged 15 to 19 had one or more MCH risk factors.

Although the problem of teen pregnancy is very real there have been few comprehensive strategies for addressing it.

The Project

An integrated project is underway in Durham involving the Durham YWCA, the Coalition for the Prevention of Adolescent Pregnancy, the Center for Creative Health Education at North Carolina Central University (NCCU), and the Department of Health Education of NCCU. The project was funded by the Z. Smith Reynolds Foundation.

Each of these four components will accomplish the following objectives.

The Durham YWCA Role Models Program. This component seeks to reduce the number of teen pregnancies by providing each of 100 teen participants with an adult

role model who acts as mentor, teacher, confidante, and skills developer. The adults will create opportunities for teens to learn skills in goal-setting, time management, and personal growth. A staff person will train the adults in counseling and crisis intervention.

Coalition for the Prevention of Adolescent Pregnancy. Organized seven years ago, the Coalition has 21 members, including Durham City and County Schools, the County Health Department, the Neighborhood Health Center, and the PTA Council. The Coalition will conduct parent seminars to form parent support groups, improve communication skills, explore attitudes, and deepen an understanding of the root causes of teen parenthood. A seminar program will target 50 adults initially, but will expand to reach churches, educators, health and social services, PTAs, etc.

Center for Creative Health Education. Established in January, 1986 with a grant from Z. Smith Reynolds, the Center has produced nine programs on such issues of concern to adolescents as teen pregnancy, alcohol, drugs, toxic waste, suicide, and apartheid. The programs organize teen production teams for drama, video, slides, music, and combinations of these media to be presented to schools, PTAs and community groups (one program was taped by the local cable station as part of a television special). The Center will use the same strategies to develop programs on the root causes of low self-esteem and on the consequences and causes of teen pregnancy and adolescent health problems, and to enhance critical thinking skills, decision-making and communication skills. The Center will shift from NCCU to the Durham YWCA under this project.

NCCU Department of Health Education. The Department will continue a Black male teen pregnancy project which operated last year. Identifying 57 Black adolescent boys who are opinion leaders and 50 Black fathers of children whose mothers are Black teens, the project will use organized discussion sessions to orient participants to the root causes of the problem, broaden knowledge, heighten awareness of sexuality, and formulate strategies to prevent adolescent pregnancy. A Hotline will also be implemented at NCCU. The adult group will focus on job and training opportunities as well as fulfilling a role as counselors.

Through education, role model counseling, skill development, employment, and self-esteem building, the project will work to reduce significantly the number of Durham teens who find themselves caught in the web of pregnancy and its resulting problems. ■

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- 1 N.C. Office of State Budget and Management. Total resident pregnancies by county of residence, 1985. Raleigh: June 1985.

Beware the Devilfish

Stingray Envenomation

HARRY H. SUMMERLIN, JR., M.D.

Sculling in the loose sediment of our coastal waters, sounds, brackish backwaters and river mouths there lies a non-aggressive but venomous marine animal, the stingray; known since the time of Aristotle as the devilfish.

Rays range in size from several inches up to 12 by 6 feet. Most of the seven species in the Atlantic Ocean are small, up to 12 by 18 inches. They are found lying on top of the sand or partially submerged with only the eyes, spine and part of the tail exposed. They are scavengers and bottom feeders, feeding upon worms, mollusks and crustaceans.¹

Stingray "attacks," about 2,000 per year in the United States,² are purely defensive. While wading in the shallows the unwary victim steps upon the devilfish and reflexly the powerful tail, bearing one to four stingers, whips upward. The sharp caudal spine is thrust into the foot or leg of the victim, producing a jagged puncture wound or a laceration and releasing venom into the wound.

Effects

The intense, searing, aching, deep pain quickly travels throughout the local tissues and spreads centrally. The retroserrated teeth and the powerful strike which can penetrate shoes, wet suits, flippers and even wooden boats, produces significant lacerations, depositing the stinger and venom sacs into the victim. Secondary bacterial infection is common. Fatalities have been reported, mostly in children secondary to intra-abdominal thoracic trauma.

The phosphodiesterase and serotonin-like substances produce pain that may last for up to 48 hours. Systemic manifestations may include generalized weakness, nausea, vomiting, diaphoresis, vertigo, syncope, headache, tachycardia, muscle cramps, fasciculations, paralysis, hypotension, dysrhythmias and even death.

Treatment

The treatment is immediate local cleansing with saline or sea water, then soaking in hot water to tolerance (115-120°F) for 30 to 90 minutes to relieve the pain and to attenuate the heat labile venom. Other heat labile venoms are produced by sea urchins, scorpion fish, and catfish.³

Cryotherapy is disastrous and there are no data to support the use of antihistamines or steroids.¹ Pain control with narcotics may be necessary if there are no contraindications. Local infiltration with 1% Lidocaine without epinephrine may give some pain relief.

Many times it is necessary that the devilfish spine be surgically excised. Tetanus prophylaxis is standard. Many consider prophylactic antibiotics with penicillin, first-generation cephalosporins, or trimethoprim-sulfamethoxazole to be indicated.

The best preventive technique against devilfish stings, if one must be wading in shallow waters, is to shuffle along to frighten off the shy, non-aggressive creature.

In summary, envenomation by a stingray requires prompt cleansing, soaking in hot water, pain relief with narcotics and/or 1% Lidocaine infiltration, excision of the retroserrated stinger, tetanus prophylaxis and antibiotics for secondary infection. ■



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- 2 Mills, Ho, Solbe and Trunsky. Current emergency diagnosis and treatment. Lange Medical Publications, 1985.
- 3 Emergencies. Nursing 85 books, Springhouse Corporation, 1985.

From 944 Tunnel Road, Asheville 28805.

Physician Assistants in North Carolina, 1986

A Report of a Survey Sponsored by the North Carolina Academy of Physician Assistants

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In May 1984 the *North Carolina Medical Journal* published the results of a survey of physician assistants in this state (Vonseggen WW and Bolles JF;45:304-8). This survey was conducted by the North Carolina Academy of Physician Assistants (NCAPA) in 1982 and gathered data on statistics, practice sites, salaries and related compensations, supervision models, and issues of concern to physician assistants and their employers. In 1986 the Public Education Committee of the NCAPA conducted another survey following a similar format. The purpose was to determine the present status of the profession in North Carolina and to document significant changes.

Demographics

A 75-question survey form was mailed in May 1986 to 600 physician assistants in North Carolina. This included all PAs registered with the N.C. Board of Medical Examiners (NCBME) and other physician assistants who are members of the state Academy but not required to register with the NCBME (those not in clinical positions and those employed by federal agencies such as the Veterans Administration). Three hundred ten returns were received (52%).

This is less than the 60% return in 1982, but it is more interesting to note that the survey was mailed to only 406 PAs in 1982. There has been a 48% increase in the number of physician assistants in North Carolina in the four years between 1982 and 1986.

A significant trend is in the male/female ratio. In 1982 70% of North Carolina PAs were men and 30% women. In

1986 the ratio shows a move toward parity with 58% men and 42% women. Those reporting that they have been working as PAs less than two years are divided 72% women and 28% men. Of those working from two to four years, 51% are women and 49% men, figures further indicating a trend toward a larger percentage of female PAs entering the workforce. The trend in PA program enrollment also demonstrates a shift toward the predominance of women. In the five-year period 1982-1986 the Bowman Gray Physician Assistant program enrolled 193 students of whom 80 (41%) were men and 113 (59%) were women. This program is typical of the trend in most of the programs throughout the nation.

There is still a predominance of caucasians in the profession (94%) with only 4% black and 2% others. There is also a trend toward older persons in the profession. In 1982 the average age of PAs was 33.4 years. In 1986 81% are over 30 while only 19% are under 30 years of age.

Ninety-one percent are graduates of a program of 24 or more months' duration. Two percent have had specialty training beyond the basic program.

Ninety-two percent are certified by the National Commission on Certification of Physician Assistants (an increase of 1% since 1982), even though the NCBME in 1983 dropped certification as a requirement for registration. Among those who have been working six or more years and so have had to take the comprehensive examination for recertification with the National Commission, 90% of respondents are certified. PAs and their practices apparently consider certification an important aspect of the profession although it is not a legal requirement for practice in the state. It is interesting that 70% of those responding feel passing the National Commission examination *should* be mandatory for registration.

Membership in professional organizations continues to

From the Public Education Committee, North Carolina Academy of Physician Assistants, 209 Shenandoah Drive, Winston-Salem 27103-5351.

increase. In 1982 76.5% of respondents were members of the American Academy of Physician Assistants (AAPA), and 53.4% were members of the NCAPA. In 1986 80% are members of the AAPA, 64% are members of the NCAPA, and 31% are members of a regional PA group within North Carolina. No intrastate regional groups were in existence in 1982. There are now regional chapters chartered by the NCAPA in Hickory, Greensboro, Winston-Salem, and the Lumberton/Whiteville/Wilmington area, and groups are being organized in Asheville and in the Triangle (Raleigh, Durham and Chapel Hill). An increasing number of PAs have their dues in professional organizations paid by their employers: 43% in 1982 and 50% in 1986.

Practice and Employment

There appears to be more stability in employment in 1986 than was reported in 1982. The average time in practice in 1982 was five years. Fifty-six percent of PAs in 1986 have worked more than five years. Thirty-nine percent have been in their present positions more than four years. Thirty-six percent have had only one job and 34% have had two. Nineteen percent have had three employers. There is very little change in these statistics since 1982.

This study shows that 57% of PAs are practicing in locations with populations greater than 50,000, while only 6% are in those with less than 5,000. This is consistent with national trends as reported by federal agencies. When the profession was established in 1965 it was seen as an answer to the problem of providing medical care to such underserved locales as remote and rural communities as well as inner-city sites. As more PAs have found employment in specialty practices they have moved to the urban locations of those practices. However, the number of PAs in underserved areas, according to a recent U.S. Department of Health and Human Services Report, is proportionately higher than that of physicians.

The general type of practice employing North Carolina PAs is compared in the following table:

	1982	1986
Family Practice	24% (59)	19% (59)
Internal Medicine	14% (34)	14% (42)
Emergency Medicine	10.7% (26)	7% (22)
Surgery	18.5% (45)	17% (52)
Other	32.5% (79)	43% (131)

The "other" category includes such practice sites as psychiatry, occupational medicine, OB/GYN, health clinics, and institutional care (educational, research, house staff). The practice employer configuration is as follows:

	1982	1986
Solo MD	22% (54)	21% (62)
Two MD Partnership	6.8% (16)	6% (16)

Group Practice	25% (65)	19% (54)
Hospital	27.4% (65)	29% (84)
Other (HMO, Industry, Educational)	19% (45)	25% (73)

The only significant change is in the "other" category reflecting the increased utilization of PAs in occupational medicine and the growing number of Health Maintenance Organizations (HMOs).

There is essentially no change in the percentage (63%) of physician assistants employed in positions described as mostly primary care. Most PAs have multiple areas of responsibility in their jobs. When PAs were asked to describe their principle function, 97% reported that they have clinical responsibilities, 30% administration, 33% teaching, and 15% research. This reflects a major expansion in the utilization of PAs in responsibilities beyond the clinical.

Sources of funding compare as follows:

	1982	1986
Private	52% (123)	46% (140)
State	19% (46)	18% (55)
Federal	7.6% (18)	10% (32)
Corporation	16.5% (39)	10% (32)
Other	3.8% (9)	16% (47)

"Other" includes educational institutions and reflects the most significant change. Three of the four medical schools in the state have significantly increased the number of physician assistants on their clinical and research staffs over the past four years.

Compensation and Benefits

In 1982 the reported average base salary (not including fringe benefits) for all PAs responding was \$22,436. In 1986 63% reported base salaries greater than \$25,000, with 30% earning more than \$30,000. The higher salaries are paid most often to PAs in surgical practices: 46% earn over \$30,000. Thirty-six percent of emergency medicine PAs earn more than \$30,000, and 33% of those in the "other" category report salaries greater than \$30,000. Of PAs in internal medicine practices, 31% earn more than \$30,000 and 64% earn more than \$25,000. Family practice PAs report salaries as follows: \$20,000 to \$24,999 — 47%; \$25,000 to \$29,999 — 25%; and \$30,000 or more — 22%. The scales by practice remain unchanged, but salaries have increased generally by more than 30% in the past four years. Eleven PAs (seven women and four men) reported that they work at their professional jobs on a part-time basis (20 hours or less per week). Of these, four women and two men reported their salaries to be in the \$10,000 to \$14,999 range. Two women said their salaries were \$20,000 to \$24,999. Surprisingly, two men PAs working part-time said that their salaries were \$30,000 or higher. Salary ranges appear to be higher for men than for women, with 54% of women earning

less than \$25,000 while only 23.6% of men were in this range. This may be partially due to the shorter time most women PAs have been working.

Fringe benefits provided to PAs compare in the two surveys as follows:

	1982	1986
Life insurance (no charge)	54%	51%
Life insurance (group rate)	27%	16%
Personal health insurance (no charge)	53%	50%
Personal health insurance (reduced charge)	25%	30%
Family health insurance (no charge)	16%	15%
Family health insurance (reduced charge)	39%	40%
Disability insurance paid by employer	50%	45%
Profit sharing	22%	23%
Allotment for CME paid by employer	78%	78%
Professional organization dues	43%	50%
Recertification fees	46%	50%
Malpractice coverage	86%	80%
Pension plan, IRA, long-term investments	53%	50%
Time off to attend CME events	90%	92%
Do not use vacation time for CME events	81%	90%

While there are differences of a few percentage points in some categories, most of these fringe benefits in 1986 are very similar to those reported in 1982.

In 1986 23% of PAs had written contracts with their employers. However, 84% recommended written contracts between PAs and their employers. These figures are about the same as those reported in 1982.

Even though salaries have generally improved over the past four years, 39% of the PAs responding said they needed a second job to provide sufficient income to meet their needs. In 1982 43.5% reported a need for a second job.

Supervision

All physician assistants must be registered to a primary supervisor with the Board of Medical Examiners. This physician is the person responsible for services provided by the PA. In group practices there may be additional physicians designated as back-up supervisors. These must also be registered with the Board.

The following table shows a comparison of supervisors in 1982 and 1986:

	1982	1986
One supervising physician	31.5% (76)	30% (86)
Two supervising physicians	24% (58)	18% (53)
Three supervising physicians	11.6% (28)	14% (39)
Four supervising physicians	9.1% (22)	12% (35)
Five or more supervisors	22% (53)	26% (75)

The way a physician assistant is supervised has always been a concern. Forty-seven percent have their supervising phy-

sician on site all the time. Thirty-four percent have the physician on site 50% of the time, and 14% less than 50% of the time. Only 5% have their supervisor on site one day each week. In 1982 60% reported full-time supervision, 18% half-time, 12% less than half of the time, and 3% on site only one day each week.

The following table compares the method of supervision:

	1982	1986
Daily chart review by MD	54%	62%
Weekly chart review by MD	10%	11%
Sporadic chart review	10%	11%
Phone consultation as needed	33%	16%

This demonstrates a trend toward a level of supervision more consistent with recommendations of the Board of Medical Examiners. PAs appear to be generally satisfied with the degree of supervision (88%). Six percent feel they get too little supervision, 4% too much, 1% too strict, and 1% have personality conflicts that interfere with effective supervision. Ninety-five percent of respondents report a satisfactory relationship with their supervising physicians.

Issues

In 1982 physician assistants were asked to express opinions on issues of concern to the profession at that time. Some of those issues remain current concerns. We attempted to update questions to reflect concerns about the future of the profession in light of a projected physician surplus. Seven statements were given and respondents were asked to answer with their personal attitudes. "I am concerned about the longevity of the PA profession" brought a 62% positive response and 32% negative (6% uncertain). "The projected surplus of physicians will have a negative impact on PAs" brought nearly equal responses: 44% agreed, 45% disagreed, and 11% were uncertain. "There is little vertical mobility within the PA profession": 74% agreed, 20% disagreed, and 5% were uncertain. "I am satisfied with my decision to enter the PA profession": 82% agreed, 10% disagreed, and 8% were uncertain. "I am satisfied with the current mechanism of PA certification": 70% agreed, 26% disagreed and 4% were uncertain. "I am satisfied with the current mechanism of PA re-certification": 21% agreed, 67% disagreed, and 11% were uncertain. "PAs should be more autonomous in their roles in clinical practice": 37% agreed, 51% disagreed and 12% were uncertain.

The change in utilization of physician assistants from principally primary care practices to specialties and subspecialties has given rise to some of the dissatisfaction with the re-certification process. Examinations are general in nature and oriented to primary care. The majority agree this is a good method for initial certification. Because so many PAs are employed in specialty and subspecialty practices, the primary-care-oriented examination employed by the Na-

tional Commission on Certification of Physician Assistants is viewed by many PAs to be inadequate (and unfair) for testing professional competence.

It appears that the majority of North Carolina PAs are satisfied with their dependent practitioner role which has been frequently restated as policy by the AAPA.

An improved climate of acceptance of physician assistants by the medical community of North Carolina is reflected in the current estimation of employment opportunities for PAs as compared to three years ago. The following compares responses:

	1982	1986
Much better	9.4%	13%
Slightly better	21.4%	26%
About the same	33.5%	46%
Slightly worse	23.7%	12%
Much worse	12.1%	3%

In 1982 20% reported encountering active opposition to the PA profession, but only 12% reported such encounters in 1986.

One interesting aspect of continuing training which was not reported in 1982 concerns cardiopulmonary resuscitation (CPR) and Advanced Cardiac Life Support (ACLS) certification. Ninety-nine percent reported having CPR training and 45% are current. Fifty percent of the PAs responding have had ACLS training and 15% hold current ACLS certification.

PAs appear to continue to be interested in all levels of medical concerns. Ninety-one percent reported their primary supervising physician to be a member of the North Carolina Medical Society. This is a notable increase from the 78% reported in 1982. Seventy-four percent of responding PAs said they would join the Medical Society as Associate Members if given the opportunity, compared to 81% in 1982. Perhaps the efforts of the NCAPA to establish regional chapters and thus increase the availability of continuing medical education has lessened the urgency of need for affiliation with the Society.

Physician assistants continue to feel that the NC Board of Medical Examiners should have a formal advisory committee to assist in all matters pertaining to PAs (96% of responders), and overwhelmingly agree that such a com-

mittee should be composed of a combination of PAs, supervising physicians, and representatives from the two PA training programs in North Carolina. It is good to note that in the past two years informal meetings have been taking place between the Board of Medical Examiners and the Board of Directors of the North Carolina Academy of Physician Assistants. These have resulted in improved communications in both directions and mutually beneficial exchange.

Summary

The 1986 NCAPA Survey confirms that the physician assistant profession is a rapidly growing, highly effective, essential element in medical care in the State of North Carolina. Not only has the number of PAs practicing grown by 48% in the past four years, but acceptance of the concept and role of the PA is widespread among all aspects of the medical community of the state — consumers and providers alike. There are definite changes in the ways PAs are being utilized, necessitated by changes in delivery systems, advances in technology, and reimbursement by Medicare for services provided by PAs in certain settings. Action by the 99th U.S. Congress authorized that effective January 1, 1987, the practices employing PAs could be reimbursed by Medicare for services provided by physician assistants in nursing homes, in hospitals and in surgery. This action has greatly increased the potential utilization of PAs in geriatric medicine.

The results of the survey also point out areas that need further effort to improve. These include better modes of supervision, increased compensation appropriate to higher educational standards, and increased professional expectations. It is hoped that the data gathered will be helpful to physicians who may be considering hiring physician assistants.

Further information may be obtained from:

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Contraindications: Known hypersensitivity to the drug.

Warnings: Warn patients that mental and/or physical abilities required for tasks such as driving or operating machinery may be impaired, as may be mental alertness in children, and that concomitant use with alcohol or CNS depressants may have an additive effect. Though physical and psychological dependence have rarely been reported on recommended doses, use caution in administering to addiction-prone individuals or those who might increase dosage. Withdrawal symptoms (including convulsions) reported after abrupt cessation of extended use of excessive doses are similar to those seen with barbiturates. Milder symptoms reported infrequently when continuous therapy is abruptly ended. Avoid abrupt discontinuation, gradually taper dosage.

Usage in Pregnancy: Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Precautions: In the elderly and debilitated, and in children over six, limit to smallest effective dosage (initially 10 mg or less per day) to preclude ataxia or oversedation, increasing gradually as needed and tolerated. Not recommended in children under six. Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider individual pharmacologic effects, particularly in use of potentiating drugs such as MAO inhibitors and phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions (e.g., excitement, stimulation and acute rage) have been reported in psychiatric patients and hyperactive aggressive children. Employ usual precautions in treatment of anxiety states with evidence of impending depression, suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation have been reported very rarely in patients receiving the drug and oral anticoagulants, causal relationship has not been established clinically. Due to isolated reports of exacerbation, use with caution in patients with porphyria.

Adverse Reactions: Drowsiness, ataxia and confusion may occur, especially in the elderly and debilitated. These are reversible in most instances by proper dosage adjustment, but are also occasionally observed at the lower dosage ranges. In a few instances syncope has been reported. Also encountered are isolated instances of skin eruptions, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased libido—all infrequent and generally controlled with dosage reduction, changes in EEG patterns (low-voltage fast activity) may appear during and after treatment, blood dyscrasias (including agranulocytosis), jaundice and hepatic dysfunction have been reported occasionally, making periodic blood counts and liver function tests advisable during protracted therapy.

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Reflections on Infections by the Sea

Or Another Form of Seasickness

Paul Becherer, M.D.

And I'm never, never sick at sea!
 What, never?
 No, never.
 What, *never*?
 Hardly, ever!

Sir William S. Gilbert
H.M.S. Pinafore, Act 1

Vibrio organisms which are distributed throughout much of the surface waters of the world have for decades been associated with gastrointestinal illnesses. Recently a group of halophilic (salt requiring) *Vibrio* species has been implicated in serious soft tissue infections in people along the Atlantic and Gulf Coast including the coast of the Carolinas. These gram negative, curved, encapsulated, flagellated rods such as *Vibrio vulnificus*, *V. parahaemolyticus*, and *V. alginolyticus* are common inhabitants of the coastal waters, thriving during the summer and fall in environments of relatively low salinity.

Vibrio Infections

In immunocompromised patients such as those with chronic liver disease, leukemia, diabetes mellitus, and those receiving steroid therapy, *Vibrio parahaemolyticus* and *V. vulnificus* have the ability to cross the intestinal mucosa and invade the blood stream. This occurs after ingestion of raw, contaminated filter feeders such as oysters. Instead of presenting with gastrointestinal symptoms, patients so afflicted develop dramatic chills, fevers followed by hypotension (30%), and, over the course of one to two days, cutaneous foci (75%). These cutaneous lesions erupt as erythematous tender foci predominantly on the lower extremities and rapidly evolve to vesicles before eventually becoming necrotic ulcers. Cultures are occasionally positive for the *Vibrio* species, and pathology shows necrotizing vasculitis which leads to tissue ischemia and bacterial invasion. *V. vulnificus* has been demonstrated to make an exotoxin which is cytolytic and increases vascular permeability. It is probably responsible for some of these manifestations.

From the Division of Nephrology, the University of North Carolina School of Medicine, Chapel Hill 27514.

More commonly, *Vibrio* infections occur as a consequence of contamination of minor wounds, or by direct inoculation, when patients are handling marine life such as oysters or shrimp. These creatures contain 10^5 organisms per gram of meat. Erythema, swelling, and ecchymosis quickly develop, with some infections leading to necrosis of the skin and the subcutaneous fat due to the necrotizing vasculitis. As noted, those with underlying disease are more likely to become bacteremic leading to hypotension and toxicity.

Therapy

Successful therapy of fulminant disease requires early recognition of the possibility of halophilic *Vibrio* species as a potential etiology, and it requires quick action. Routine supportive care with massive fluid resuscitation is often needed. Standard mediums such as MacConkey's agar which contains sodium chloride, or Thiocitrate bile salt (TCBS) medium, will support the organism. Since these organisms ferment lactose, they may be disregarded as non-enteric pathogens unless fully identified. While *V. vulnificus* is sensitive to penicillins, the other organisms may be resistant. Therefore treatment with tetracycline or chloramphenicol, and potentially erythromycin or an aminoglycoside, may be required.

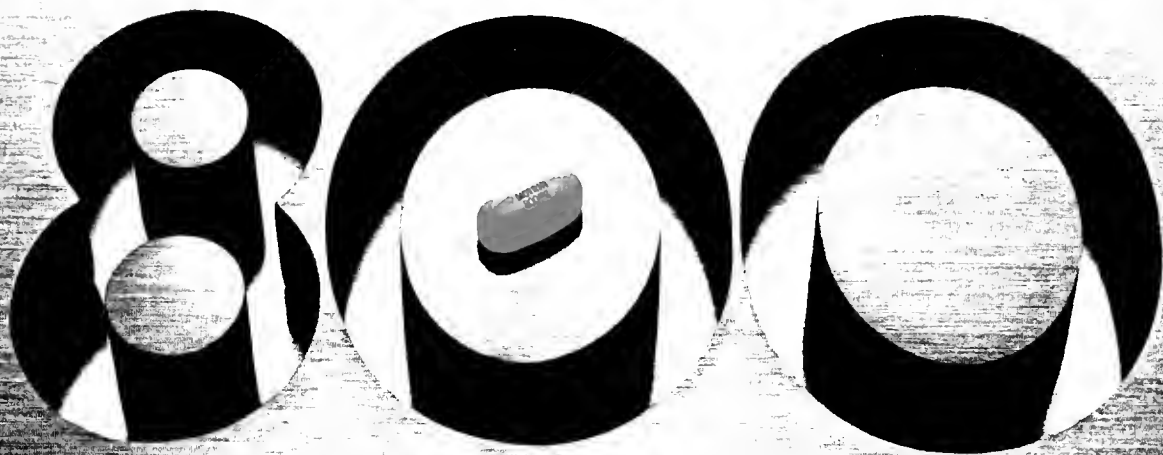
In addition, surgical débridement and even amputation of the affected limb may be necessary. Despite appropriate treatment, nearly 50% of those who become bacteremic, i.e. those with an underlying illness, succumb. Therefore those who are immunocompromised should be warned about consumption of raw seafood and about unnecessary exposure to marine crustaceans. ■

References

- 1 Chang W and Pien F. Marine-acquired infections: hazards of the ocean environment. *Postgrad Med* 1986;80:30-2.
- 2 Howard R, et al. Necrotizing soft tissue infections caused by marine *Vibrios*. *Surgery* 1985;98:126-30.
- 3 Bonner J, et al. Spectrum of *Vibrio* infections in a Gulf Coast community. *AIM* 1983;99:464-9.
- 4 Gray L and Kreger A. Mouse skin damage caused by cytolysin from *Vibrio vulnificus* and by *V. vulnificus* infection. *J Inf Dis* 1987;155:236-40.

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Brief Summary. Consult the package literature for prescribing information.

Indications and Usage: Keflet™ Tablets (cephalexin, Distal) are indicated for the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

Respiratory tract infections caused by *Streptococcus pneumoniae* and group A β hemolytic streptococci (Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. Keflet is generally effective in the eradication of streptococci from the nasopharynx, however, substantial data establishing the efficacy of Keflet in the subsequent prevention of rheumatic fever are not available at present.)

Otitis media due to *S. pneumoniae*, *Haemophilus influenzae*, staphylococci, streptococci, and *Neisseria californiens*

Skin and skin structure infections caused by staphylococci and/or streptococci

Bone infections caused by staphylococci and/or *Proteus mirabilis*

Genitourinary tract infections, including acute prostatitis, caused by *Escherichia coli*, *P. mirabilis*, and *Klebsiella sp.*

Note:—Culture and susceptibility tests should be initiated prior to and during therapy. Renal function studies should be performed when indicated.

Contraindications: Keflet is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: BEFORE CEPHALEXIN THERAPY IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE CONCERNING PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS AND PENICILLINS. CEPHALOSPORIN C DERIVATIVES SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS.

SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE EPINEPHRINE AND OTHER EMERGENCY MEASURES.

There is some clinical and laboratory evidence of partial cross allergenicity of the penicillins and the cephalosporins. Patients have been reported to have had severe reactions (including anaphylaxis) to both drugs.

Any patient who has demonstrated some form of allergy, particularly to drugs, should receive antibiotics cautiously. No exception should be made with regard to Keflet.

Pseudomembranous colitis has been reported with virtually all broad spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins). Therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life threatening.

Treatment with broad spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Usage in Pregnancy:—Safety of this product for use during pregnancy has not been established.

Precautions: General:—Patients should be followed carefully so that any side effects or unusual manifestations of drug idiosyncrasy may be detected. If an allergic reaction to Keflet occurs, the drug should be discontinued and the patient treated with the usual agents (eg, epinephrine or other pressor amines, antihistamines, or corticosteroids).

Prolonged use of Keflet may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematology studies or in transfusion cross matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Keflet should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

Indicated surgical procedures should be performed in conjunction with antibiotic therapy.

As a result of administration of Keflet, a false positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinistest® tablets but not with Tes Tape® (Glucose Enzymatic Test Strip, USP Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy—Pregnancy Category B—The daily oral administration of cephalexin to rats in doses of 250 or 500 mg/kg prior to and during pregnancy, or to rats and mice during the period of organogenesis only, had no adverse effect on fertility, fetal viability, fetal weight, or litter size. Note that the safety of cephalexin during pregnancy in humans has not been established.

Cephalexin showed no enhanced toxicity in weanling and newborn rats as compared with adult animals. Nevertheless, because the studies in humans cannot rule out the possibility of harm, Keflet should be used during pregnancy only if clearly needed.

Nursing Mothers—The excretion of cephalexin in the milk increased up to 4 hours after a 500-mg dose, the drug reached a maximum level of 4 µg/mL, then decreased gradually, and had disappeared 8 hours after administration. Caution should be exercised when Keflet is administered to a nursing woman.

Adverse Reactions: Gastrointestinal—Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely. The most frequent side effect has been diarrhea. It was very rarely severe enough to warrant cessation of therapy. Dyspepsia and abdominal pain have also occurred. As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.

Hypersensitivity—Allergic reactions in the form of rash, urticaria, angioedema, and, rarely, erythema multiforme, Stevens Johnson Syndrome, or toxic epidermal necrolysis have been observed. These reactions usually subsided upon discontinuation of the drug. Anaphylaxis has also been reported.

Other reactions have included genital and anal pruritus, genital moniliasis, vaginitis and vaginal discharge, dizziness, fatigue, and headache. Eosinophilia, neutropenia, thrombocytopenia, and slight elevations in SGOT and SGPT have been reported.

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Medical Student's Disease Syndrome

Gary L. Roark

I learn of all these pathogens in classes every day.
It's amazing how our bodies learn to keep those germs at bay.
Yet, every time I turn around, I get a hint or two,
Exotic signs and symptoms — it's no ordinary flu.
My teeth will start to itch, or it's a cramp down in my spleen.
So many things that it could be . . . it makes me sorta green.

I stay awake throughout each class. My notes, I later check.
But this lecture chair is killing me! There's a pain back in my neck.
I begin to think that what I have is spinal meningitis,
Or some awful, dreadful illness that they tell us just to frighten us.
Or maybe it's a little one, like osteosarcoma.
But wait a minute! Now I know: it's Medical Student Syndroma!

Or, take the time just yesterday, in the middle of a test:
I'd remembered only half the stuff, forgotten all the rest.
Have I hippocampal lesions, or an infection like frambesia?
Have I epileptic seizures, or is it retrograde amnesia?
Oh, shoot! It'd put my mind at rest, or maybe more at ease,
If I could just remember what this blasted, darn Disease is!

From Bowman Gray School of Medicine, Wake Forest University,
Winston-Salem 27103.



Seated, left to right, Neil P. Dubner, M.D., Medical Director; D. Wilfred Abse, M.D.; James K. Barnes, M.D.; Ronald L. Myers, M.D. Standing, left to right, Orren LeRoyce Royal, M.D.; Morgan E. Scott, M.D.; Don L. Weston, M.D.; Arthur E. Kelley, M.D.; G. Paul Hlusko, M.D.; Hal G. Gillespie, M.D.; Basil E. Roebuck, M.D.

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Letters to the Editor

On the science and the art of medicine

To the Editor:

Physicians do not treat disease. They treat individuals. To be a truly good physician one needs more than a knowledge of medicine. In recent decades there has been a growing belief that the emphasis on science would ultimately render obsolete individualism and subjectivity, but despite the dramatic technological advances it remains the fate of physicians to experience uncertainty and doubt, for it appears certain that the human condition will never be totally explained in biochemical terms. The practice of medicine must therefore embrace the scientific method, but the art of medicine should not be abandoned.

Physicians, like all other humans, wish for the certainty that science appears to promise, but science ignores values and individuality.

The words of Hippocrates are still valid. "Life is short, the art long, the occasion fleeting, experience fallacious, and judgments difficult." Medicine must embrace more than science.

The rise of commercialism, the proliferation of for profit oriented facilities, advertising, cost containment, third party payors, and the malpractice environment have emphasized technology rather than humanism. This has resulted in a depersonalization of the doctor-patient relationship a loss of samaritanism. The good physician must, however, be more than a competent technician, more than a cost effective health care provider.

The dramatic technological advances have, to the surprise of many, created many ethical and moral questions for which science has no answers. Central issues involve freedom, self determination, quality of life. The rights and obligations of both physicians and patients must be addressed. Consent, and the increasing involvement of patients, their families, and their physicians in providing, withholding, accepting or refusing treatment, are not scientific issues. Science provides a strong and solid intellectual basis, and may even be central to the practice of medicine, but alone it is not enough.

Walter S. Feldman, M.D., J.D., F.C.L.M.
6500 Raquet Wood Court
Charlotte 28226

A comment on Dr. Linfors's forum

To the editor

As a newcomer to North Carolina, I was particularly pleased to read The Physician's Forum "Policing the Practice of Medicine." Granting that each state tackles these problems in a little different way, it may be beneficial to address this issue of physician discipline by organizing it

into three areas of problem physicians — "the sick, the bad, and the ignorant."

The Sick. These individuals should be treated. Alcoholism and substance abuse are diseases which can be treated. We should offer no less compassion and assistance to our colleagues than we would to our patients, even though they do not spontaneously rush to us for help.

The Bad. Some physicians unfortunately become involved in illegal activities. Dealing with this is generally a function of the state, and it is not an option for us to decide what we want to do when someone has broken the law.

The Ignorant. Some physicians are not adequately trained or have not kept current in the field. While medical societies certainly may offer continuing education, and may even serve to speak to the adequacy of certain courses in organized educational efforts, initial requirements of credentialing for license are a state function. The issue of assessing continued current competence at some later date after initial training is a very controversial topic which I shall not address here.

The above tripartite organization may be useful in dealing with the question of physician discipline. Difficulties frequently arise when the distinctions between Sick/Bad and Sick/Ignorant become very blurred, such as the physician who writes illegal prescriptions for himself or others to support his own addiction, and the physician who may be intellectually inadequate because of mental illness or dementia. Keeping these issues focused and separate can make the approach to them more logical and effective.

I do applaud our society for addressing these major issues. However, longing for the good old days and "simple personal ethics," while desirable, are not enough to satisfy even the demands of the 1980s let alone the demands of the 1990s. At this time there are extremely effective models for dealing with physical substance abuse and mental illness that have been developed and proven by other states. It is the one part of the Sick/Bad/Ignorant issue of physician discipline that we as a society can and should be addressing vigorously.

Brian R. Nagy, M.D.
Medical Director
Mecklenburg Mental Health Center
Charlotte 28211

Ophthalmology Guidelines

To the Editor:

Please find enclosed a letter which I recently composed as President of the Eastern Carolina Ophthalmological Society and forwarded to all members of the Board of Medical Review of North Carolina as well as to the Members of the

Medical Review Committee of MRNC. The letter urges adoption of strict pre and post surgical criteria for cataract surgery patients. These guidelines are based upon recommendations from the American Academy of Ophthalmology and are presently being considered in various similar forms in all fifty states.

These guidelines were evaluated extensively by the North Carolina State Ophthalmological Society where even tighter restrictions upon the State's ophthalmologists were encouraged. The State Ophthalmological Society felt that there was a strong need for stringent criteria governing the pre and post surgical care of cataract surgery patients — the most common surgical procedure in America.

I believe my accompanying letter is self-explanatory as it urges all members of the Medical Review Committee and Board members of MRNC to adopt these stringent guidelines intact. This is the first time that the professionals in a medical specialty area have come together and requested the imposition of tight controls on their own practice of medicine. This is an unprecedented step which most of the ophthalmologists in this state feel is necessary to ensure a minimum level of quality to the citizens of our state.

Scott P. Bowers, M.D.
Carolina Clinic, Inc.
1700 S. Tarboro Street
Wilson 27893

Dr. Bowers's letter to MRNC:

I am writing to you as president of the Eastern Carolina Ophthalmological Society. It has recently come to the attention of the society that a list of procedures has been developed by HCFA for which 100% prospective review must be performed by the various state PRO agencies. It seems likely that cataract surgery will be high on this list and will, therefore, be subject to 100% prospective review. The Eastern Carolina Ophthalmological Society would like to formally endorse the PRO guidelines recently proposed by the North Carolina State Society of Ophthalmology.

The State Ophthalmological Society has very carefully considered this issue and proposed a set of PRO guidelines which insure the highest quality of care for all patients in the State of North Carolina. I am sure you have received a copy of these proposed guidelines from the State Ophthalmological Society and have reviewed them in detail. Briefly, these guidelines insure that every patient who undergoes cataract extraction in the state of North Carolina has been examined preoperatively by his operating surgeon. The old medical school tenet "when all else fails, examine the patient" has been almost totally abandoned by certain eye surgeons in this state who routinely operate on patients they have never examined. This is unthinkable, but unfortunately occurs on a wholesale basis in certain areas of the state. Patients are often sent in with "preoperative examinations" performed by nonphysicians. This is not only improper and a violation of the Ethics Code of the American Academy

of Ophthalmology, but is quite possibly illegal. The North Carolina Department of Human Resources, Division of Faculty Services, has issued a booklet entitled "Rules and Regulations Governing the Licensure of Ambulatory Surgical Facilities." Page eight of this manual states "any patient undergoing general or regional anesthesia shall, prior to the surgery, have a history and physical examination, relative to the intended procedure, performed by a licensed physician." From a quality of care point of view, it is imperative that patients be examined by their operating surgeon before they are subjected to surgical procedures. This principle is so basic to good medical care that it should go without saying. Unfortunately, certain providers in the state have found it economically advantageous to do huge volumes of surgery on patients that they have never examined and have no intention of ever seeing again.

The surgeon is asked to certify that the patient is truly in need of the surgery — not simply because of the presence of a lenticular opacity. A basic visual acuity guideline has been adopted which is fair and reasonable. Those patients with 20/40 vision or better should probably not routinely be scheduled for cataract surgery. With 20/40 vision, any elderly patient can hold an unrestricted driver's license in all fifty states of the union and drive the maximum speed limit on interstates day or night. These guidelines were developed by all fifty states decades ago as the minimum visual acuity for the safe operation of a motor vehicle. This visual acuity level has real value in that it was not arbitrarily picked out of thin air, but has been used as a benchmark for minimum visual requirements by all fifty states for many many years. When patients have visual acuity at 20/50 or worse, their driving privileges begin to be curtailed such that their mobility is restricted. This is probably a reasonable point at which to consider cataract extraction for the elderly patient. If a patient can drive to an outpatient surgical center day or night with an unrestricted driver's license (visual acuity 20/40 or better), it is most difficult to justify subjecting this patient to a surgical procedure. Certain exceptions should be made — i.e. for commercial airline pilots or persons with occupations demanding visual acuity at or better than 20/40. These patients should be considered on a case by case basis, and a second opinion would probably be indicated in all patients with a visual acuity of 20/40 or better.

The PRO guidelines also require that surgeons not undertake surgical responsibility for patients and then abandon them to the care of nonmedical technicians, optometrists, nurses or other nonphysicians. The postoperative care of cataract surgery patients is within the unique competence of an ophthalmologist, and the operating surgeons should and must provide adequate postoperative care to their patients. This is a basic tenet of medicine which should not be overlooked in the field of cataract surgery. Chiropractors do not routinely assume the postoperative care of laminectomy or brain surgery patients; podiatrists do not routinely assume the postoperative care of arthroscopy or hip replacement patients; dentists do not routinely assume the post-

operative care of head and neck surgery patients or oral cancer patients; and cosmetologists do not routinely assume the postoperative care of patients who have had procedures for various types of dermal pathology — despite the fact that these activities may be technically legal. If a physician is simply too busy to provide adequate postoperative care to his patient, he should not be allowed to do the surgery in the first place. This is a simple quality of care issue which is true for all medical specialties. This is 1986 — not 1940. There are several geographic areas of the state and there are *no areas* in North Carolina where a patient is not within ten to fifteen minutes driving time of a Board certified ophthalmologist. Arguments which promote the provision of all postoperative care of cataract surgery patients by nonmedical technicians (i.e. optometrists) often tout the "increased convenience" that this affords these patients. It is quite obvious that these arguments are made to facilitate certain unscrupulous surgeons who routinely undertake surgical responsibility for patients who they have not examined preoperatively and have no intention of ever seeing during any of the postoperative period. From the point of view of quality of care, it is always in the patient's *best interest* to have his postoperative care provided by his operating surgeon. Because there are so many able and qualified Board certified ophthalmologists in this state who are willing to adhere to these standards, this should be the minimum acceptable level of quality offered to the elderly citizens of the State of North Carolina.

The last provision in the PRO guidelines proposed by the North Carolina State Ophthalmological Society entails a provision by which the signed PRO prior approval form must be received in the office of Peer Review of North Carolina and reviewed prior to the issuance of an approval for the patient's surgery. This provision is designed to insure that all patients who are considered for cataract surgery are reviewed *in writing* by impartial reviewers of the PRO prior to the surgery. Because the physician's signature will be required on this form, it would effectively prohibit economically interested parties or nonmedical technicians (i.e. optometrists or nurses) from phoning Peer Review of North Carolina and obtaining prior approval for one of these high volume surgeons. In addition, a week or two delay in receiving a written approval from Peer Review of North Carolina would allow the patient to consider the surgery carefully with his family and friends and decide whether the surgery was indeed necessary. As you know, many patients considering elective surgery properly decline such surgery after careful consideration. If surgeons are allowed to examine elective surgery patients at 9 o'clock in the morning and have them on the operating table at 10:15 in the morning, significant volumes of patients will thus be generated — denying these patients an adequate time to reflect and consider their therapeutic options. Therefore, the proposal to demand a written prior approval form signed by the operating surgeon is another step in guaranteeing the highest quality of care for all patients.

The Eastern Carolina Ophthalmological Society has gone through the above mentioned PRO proposals point by point and strongly endorses each one. The Eastern Carolina Ophthalmological Society had its most recent meeting on December 10, 1986 in Greenville and when the issue of these proposed PRO guidelines was put forth for final consideration, it was adopted unanimously without a single dissenting vote. I was asked by the Society members at that point to write a letter of support for these proposed PRO guidelines from the Eastern Carolina Ophthalmological Society to Peer Review of North Carolina. It is strongly felt by all members of the Society that these guidelines will greatly improve the quality of care for patients here in North Carolina and largely eliminate much of the unnecessary or ill-advised surgery now being performed in this area. These guidelines will insure that every elderly patient in the State of North Carolina — no matter where they are from or who they see — will receive an adequate preoperative examination and will truly be in need of the surgery proposed. In addition, the patient will receive adequate preoperative care by his operating surgeon and will be given time to reflect and consider his therapeutic options before agreeing to the elective surgery. Although this two page check-off form will take a minute or two to fill out and sign for each proposed cataract surgery patient and does represent a moderate inconvenience for the ophthalmologists of North Carolina, it is strongly felt by the Society members that any weakening of these proposed guidelines could drastically cut the quality of care offered to the citizens of the State of North Carolina.

Peer Review of North Carolina has a great opportunity to elevate the level of care for patients in this state and to eliminate many abuses which have allowed the wholesale performance of unnecessary procedures and abandonment of surgical patients by their operating surgeons. The Eastern Carolina Ophthalmological Society strongly encourages you to adopt the PRO guidelines proposed by the North Carolina State Ophthalmologic Society *intact*. Please do not hesitate to call my office at the above listed address and number if I can provide any further information to you which you might find helpful in hammering out final PRO guidelines for cataract surgery.

Respectfully submitted

Scott P. Bowers, M.D.

President

Eastern Carolina Ophthalmological Society

Insurance snafu

To the Editor:

Here is a perfect example of how bureaucracy (and occasionally computers) make us old, or in some cases, dead, before our time. I have enclosed a copy of the letter I received, as well as a copy of my return letter. I would be interested in knowing if many of our co-workers have experienced similar Medicare boo-boos.

Dear Provider:

This claim contains services for 9-1 to 10-28-86 which is after the patient's date of death of 8-00-86.

Please verify and furnish us corrected information for any/all of the following:

- 1 Date of Death
- 2 Date(s) of Service
- 3 Health Insurance Claim Number
- 4 Beneficiary Name

If the information needed cannot be obtained prior to 3-11-87 the claim will be processed on the basis of the information on hand.

Sincerely,
Assistant Claim Supervisor

Dear Assistant Claim Supervisor:

I am writing on behalf of both Blowing Rock Medical Clinic and Blowing Rock Hospital. Somehow a remarkable error has occurred. Despite your records to the contrary, the patient is indeed *alive* and a patient in the Extended Care Facility here in Blowing Rock. Now, the date of death you have listed is 8-00-86. I have never seen any such date for any month. Her date of birth is 7/18/27. If you would like, I will send a Polaroid picture of her for your files. I am sure her family would be most interested to know of her demise last year and would wonder whom they had been visiting, lo these many months.

Please let us know if this snafu is not correctable.

Sincerely,
John D. Davis, Jr., M.D.

About the journal's new look

To the Managing Editor:

Congratulations.

As I was checking the March journals, I noticed the change in North Carolina's cover. It was no longer blue and white. Your new cover is very impressive.

Once again, congratulations and keep up the good work.

Miriam Polich, Executive Vice President

State Journal Group

State Medical Journal Advertising Bureau, Inc.

711 South Boulevard

Oak Park, IL 60302

To the Managing Editor:

I must compliment you on the redesign of your journal!

Susan Flanigan Gold

Managing Editor

Missouri Medicine

113 Madison St.

Jefferson City, MO 65102



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Harry Jay Kicherer (R), 885 St. Andrews Dr., Pinehurst 28374

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Lawrence Curtis Bandy (GYN), ECU School of Med., Dept. of OB-GYN, Greenville 27834

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Charmaine Delores Gray (PD), PO Box 238, Hookertown 28538

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Continuing Medical Education

Please note: The Continuing Medical Education Programs at Bowman Gray, Duke, East Carolina (ECU) and UNC Schools of Medicine, Dorothea Dix, and Burroughs Wellcome Company are accredited by the American Medical Association. Therefore CME programs sponsored or cosponsored by these schools automatically qualify for AMA Category I credit toward the AMA's Physician Recognition Award, and for North Carolina Medical Society Category A credit. Where AAFP credit has been obtained, this also is indicated.

IN STATE

May 13

Common Diagnostic Problems in Surgical Pathology: A Practical Approach

Place: Greenville

Fee: \$55

Credit: 7 hours Category I AMA

Info: The Office of CME, ECU School of Medicine, P.O. Box 7224, Greenville 27835-7224. 919/758-5200, ext 208

May 15

Adolescent Health Issues: The New Morbidities

Place: Durham

Credit: 8 hours Category 1 AMA

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

May 19

Infectious Disease Seminar

Place: Asheville

Credit: 4 hours Category 1 AMA

Info: Dr. Felix A. Sarubbi, 704/298-7911 or Dr. Harry A. Gallis, 919/684-3279

May 22

4th Annual Eye Conference — "Ocular Tumors"

Place: Winston-Salem

Info: Kirk Huske, Bowman Gray School of Medicine of Wake Forest University, Graylyn Conference Center, Winston-Salem 27103. 919/748-3971

June 3

Duke CME Series

Place: Durham

Credit: pending

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

June 5-7

Duke Eye Center Alumni Spring Meeting

Place: Chapel Hill

Credit: 8 hours Category 1 AMA

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

June 9

1987 Series — Duke Tuesday

Place: Durham

Credit: 5 hours Category 1 AMA

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

June 10

Jay M. Arena Symposium: A Day of Toxicology and Poison Prevention

Place: Durham

Credit: 6 hours Category 1 AMA

Fee: \$10

Info: Chris Rudd, Pharm.D., 919/681-4574

June 11-13

34th Annual Mountaintop Medical Assembly

Place: Waynesville

Info: George W. Brown, M.D., Mountaintop Medical Assembly, Waynesville 28786. 704/456-6021

June 15-17

Surgery for Coronary Artery Disease

Place: Durham

Fee: \$460 ACC members; \$525 others

Credit: 17 hours Category 1 ACCME

Info: Registration Secretary, Extramural Programs Dept., American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 800/253-4636; in MD or AK 301/897-5400

July 3-5

17th Annual Sports Medicine Symposium

Place: Wrightsville Beach

Info: W. Alan Skipper, 919/833-3836 or 800/722-1350

July 13-15

U.S. Olympic Festival Sports Medicine Conference: Part II, Athletic Injury Prevention and Treatment

Place: Durham

Credit: pending

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

July 13-17

29th Annual Postgraduate Course/Morehead Symposium

Place: Durham

Credit: 26 hours Category 1 AMA; AAFP 24.75 prescribed

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

July 27-31

10th Annual Radiology Postgraduate Course

Place: Atlantic Beach

Credit: 20 hours Category 1 AMA

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

August 14-18

Family Physicians Weekend

Place: Wrightsville Beach, NC

Credit: 12 hours AAFP

Info: Paula Baker, Meeting Coordinator, North Carolina Academy of Family Physicians, P.O. Box 18469, Raleigh 27619. 919/781-6467

Nursing

Except where otherwise noted, contact Nettie Wilburn, CPS, Office of Continuing Education, University of North Carolina, Chapel Hill 27514. 919/966-3638.

May 13-14

The Systematic Process of Instructional Development

Place: Chapel Hill

Credit: 13.2 CEUs pending

Fee: \$110

June 1-5

Preparation for NCLEX-RN

Place: Chapel Hill

Credit: 3.39 CEUs

Fee: \$75 UNC-CH students; \$85 others

June 1-19

Summer Institute: Gerontology for Nurse Educators

Place: Chapel Hill

Credit: 3 CEUs

Fee: \$3

OUT OF STATE**May 8-10**

6th Annual MCV Cardiology Conference

Place: Williamsburg, VA

Fee: \$325

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

May 11-15

Consultant's Course in Cardiology

Place: New York, NY

Credit: 32 hours Category 1 AMA

Fee: \$425 ACC members; \$525 others

Info: Registration Secretary, Extramural Programs Dept., American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 800/253-4636; MD & AK, 301/897-5400 ext 226

May 14-16

Vascular Surgery 1987: Third International Vascular Symposium

Place: New York, NY

Fee: \$400

Credit: 24 hours Category 1 AMA

Info: Ann J. Boehme, Assoc. Director for CME, Long Island Jewish Medical Center, New Hyde Park, NY 11042. 718/470-8650

May 15

3rd Annual Symposium on Geriatric Medicine

Place: Norfolk, VA

Credit: 5 hours Category 1 AMA

Fee: \$35-55

Info: Elaine Halverson, EVMS-CME, P.O. Box 1980, Norfolk, VA 23501. 804/446-5243

May 16

Post Polio Syndrome Symposium

Place: Bristol, TN

Info: Ramona Miller, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

May 17

Annual Meeting, NC Chapter of American College of Surgeons

Place: Myrtle Beach, SC

Credit: 8 hours Category 1 AMA

Fee: \$50

Info: Michael C. Rowland, M.D., F.A.C.S., Secretary-Treasurer, NC-ACS, P.O. Box 2000, Pinehurst 28374. 919/295-2232

May 18-19

14th Annual Hans Berger Day and EEG Symposium

Place: Richmond, VA

Fee: \$250

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

May 19-22

Cell Calcium Metabolism '87: Physiology, Biochemistry, Pharmacology, and Clinical Implications

Place: Washington, D.C.

Info: Dr. Gary Fiskum, Dept. of Biochemistry, The George Washington University of Medicine and Health Sciences, 2300 Eye St. NW, Washington, D.C. 20037.

May 22-24

2nd Annual Duke Anesthesiology Conference: Oxygen Transport in the Clinical Setting

Place: Charleston, SC

Credit: 13 hours Category 1 AMA

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878; outside NC 800/222-9984

May 23-25

Gynecologic Urology and Pelvic Surgery

Place: Williamsburg, VA

Fee: \$260

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Sta., Richmond, VA 23298-0001. 804/786-0494

May 26-30

Fifth Annual Cardiology Update

Place: Honolulu, HI

Fee: \$395

Info: Lisa Krehbiel, 30131 Town Center Dr., Ste. 215, Laguna Niguel, CA 92677. 714/495-4499

May 30

Management of Tough Problems in Psychiatric Practice

Place: Gatlinburg, TN

Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

May 30-June 2

International Conference on Missionary Medicine

Place: St. Simons Island, GA

Fee: \$100-225

Info: Registrar, ICMM, MAP International, Box 50, Brunswick, GA 31520. 912/265-6010, ext 321

May 31-June 4

44th Annual Meeting, American Society of Hospital Pharmacists

Place: Washington, D.C.

Info: ASHP, 4630 Montgomery Ave., Bethesda, MD 20814. 301/657-3000

June 1-5

Basic Mechanisms of Cardiovascular Diseases: Implications for Prevention and Therapy

Place: London, England

Credit: 26 hours Category 1 AMA

Fee: \$425

Info: London Cardiology Course, Div. of CME-Vanderbilt, CCC-5326 Medical Center North, Nashville, TN 37232. 615/322-4030

June 2-4

Carroll Long Lecture

Place: Johnson City, TN

Info: Ramona Miller, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

June 3-7

Eleventh Annual Postgraduate Course on Rehabilitation of the Brain-Injured Adult and Child

Place: Williamsburg, VA

Fee: \$285

Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Station, Richmond, VA 23298-0001. 804/786-0494

June 4-6

Pediatric Electrocardiography, Electrophysiology and Pacing

Place: Bethesda, MD

Credit: 18 hours Category 1 AMA

Fee: \$415-\$465

Info: Learning Center, American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 301/897-5400, ext 241, or 800/253-4636

June 4-6

11th Annual Update Cardiology for the Primary Physician

Place: Charleston, SC

Credit: 19 Hours Category 1 AMA

Fee: \$335-400

Info: Registration Secretary, Extramural Programs Dept., American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 800/253-4636 (in MD and AK, 301/897-5400, ext 226)

June 5-7

16th Annual Scientific Assembly, CA Chapter of American College of Emergency Physicians

Place: Newport Beach, CA

Fee: \$250 non-members

Info: CAL/ACEP, 505 N. Sepulveda Blvd., #12-14, Manhattan Beach, CA 90266. 213/374-4039

June 6-11

Advanced Techniques in MRI

Place: Kiawah Island, SC

Credit: 14 hours Category 1 AMA

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878; outside NC 800/222-9984

June 7-10

Doppler and 2-D Echocardiography

Place: Chicago, IL

Credit: 39 hours Category 1 AMA

Info: Lisa Krehbiel, Inst. for Medical Studies, 30131 Town Center Dr., Laguna Niguel, CA. 714/495-4499

June 8-10

Aggressive Management of Cardiovascular Emergencies

Place: Bethesda, MD

Credit: 17 hours Category 1 AMA

Fee: \$415 members ACC; \$465 others

Info: Program Registrar, Heart House Learning Center, American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 301/897-5400, ext 241; 800/253-4636

June 9-13

4th Annual Adult Infectious Disease Seminar — Current Update

Place: Hilton Head Island, SC

Credit: 19 hours Category 1 AMA, AAFP

Fee: \$295

Info: George M. Converse, M.D., Director, Medical Education, Lloyd Noland Hospital and Health Centers, 701 Ridgeway Rd., Fairfield, AL 35064. 800/845-6131 (in SC, 800/922-7042)

June 10-13

Post-Graduate Course: Dermatology for Non-Dermatologists

Place: Myrtle Beach, SC

Credit: 15.5 hours Category 1 AMA

Fee: \$200-350

Info: Div. of Dermatology, Box 3135, Duke University Medical Center, Durham 27710. 919/684-2504

June 11-13

Advanced Echocardiography and Doppler Ultrasound 1987
 Place: San Diego, CA
 Credit: 21 hours Category I AMA
 Fee: \$295-450
 Info: Registration Secretary, Extramural Programs Dept, American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814 301/897-5400, ext 241; 800/253-4636

June 11-13

Current Advances in Pediatric Practice
 Place: Gatlinburg, TN
 Credit: 12 hours Category I/PREP, AAP, AAFP
 Info: Dr. Sandra Loucks, University of Tennessee Memorial Research Center and Hospital, Dept. of Pediatrics, 1924 Alcoa Highway, Knoxville, TN 37920. 615/544-9331

June 14-20

33rd Annual Family Practice Review
 Place: YMCA of the Rockies, Estes Park, CO.
 Info: University of Colorado School of Medicine, Office of Continuing Medical Education, 4200 East 9th Ave., Box C-295, Denver, CO 80262. 303/394-5195

June 15-17

Management of Clinically Localized Prostate Cancer
 Place: Bethesda, MD
 Credit: 14 hours Category I AMA
 Info: Nancy Cowan, Prospect Associates, 1801 Rockville Pike, Suite 500, Rockville, MD 20852. 301/468-6555

June 15-18

18th Annual Internal Medicine Symposium
 Place: Kiawah Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

June 15-18

4th Annual Advanced Colposcopy and Basic and Advanced Gynecologic Laser Surgery
 Place: Hilton Head, SC
 Info: Educational Associates, P.O. Box 24772, Winston-Salem 27114. 919/760-2788

June 21-28

3rd Annual Advances in Internal Medicine
 Place: Hilton Head Island, SC
 Credit: 25 hours Category I AMA
 Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878; outside NC 800/222-9984

June 22-26

The Physician in Management
 Place: Colorado Springs, CO
 Credit: 31 CME credits
 Info: Sherry Mason, American Academy of Medical Directors, 4830 W. Kennedy Blvd., Suite 648, Tampa, FL 33609. 813/873-2000

June 29-July 3

Pediatric Infectious Disease in the Office Practice
 Place: Aspen, CO
 Info: University of Colorado School of Medicine, Office of Continuing Medical Education, 4200 East 9th Ave., Box C-295, Denver, CO 80262. 303/394-5195

June 29-July 4

Midsummer Family Practice Digest
 Place: Myrtle Beach, SC
 Credit: 30 hours AAFP
 Info: Paula Baker, Meeting Coordinator, North Carolina Academy of Family Physicians, P.O. Box 18469, Raleigh 27619. 919/781-6467

July 9-11

Clinical Obstetrics
 Place: Kiawah Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

July 13-16

Clinical Cardiology
 Place: Kiawah Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

July 16-18

3rd Annual Berkshire Medical Conference: Advances in Cardiology
 Place: Hancock, MA
 Credit: 16 hours Category I AMA
 Fee: \$295
 Info: Berkshire AHEC, 725 North St., Pittsfield, MA 01201. 413/499-4161, ext 2417

July 17-19

Practical Internal Medicine: Selected Topics for the Internist
 Place: Virginia Beach, VA
 Fee: \$295
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48, MCV Station, Richmond, VA 23298-0001

July 22-26

Critical Care Medicine
 Place: Kiawah Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

July 23-25

3rd Annual Berkshire Medical Conference: Common Emergencies in General Medicine
 Place: Hancock, MA
 Credit: 16 hours Category I AMA
 Fee: \$295
 Info: Berkshire AHEC, 725 North St., Pittsfield, MA 01201. 413/499-4161, ext 2417

July 24-26

The 9th Annual Pediatric Primary Care Conference: Pediatrics at the Beach
 Place: Virginia Beach, VA
 Credit: 14.25 hours Category I AMA
 Fee: \$275
 Info: Ann Potter, Office of CME, Medical College of Virginia, Box 48, MCV Station, Richmond, VA 23298-0001

July 27-29

Pediatric Update 1987
 Place: Kiawah Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

August 2-7

Diagnostic Electron Microscopy: Annual Meeting, Electron Microscopy Society of America
 Place: Baltimore, MD
 Info: John Shelburne, M.D., or Victor Roggli, M.D., Dept. of Pathology, Duke University and V.A. Medical Centers, Durham 27710. 919/286-6925

August 3-8

Your Practice, Your Money, Your Family
 Place: Hilton Head Island, SC
 Info: Div. of CME, Medical College of Georgia, Augusta, GA 30912-6450. 404/828-3967

August 6-9

Summer Retreat: Practical Issues in Primary Care
 Place: Virginia Beach, VA
 Fee: \$350
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48 MCV Station, Richmond, VA 23298-0001. 804/786-0494

August 14-16

Primary Care of the Female Patient
 Place: Virginia Beach, VA
 Fee: \$295
 Info: Kathy Martin, Office of CME, Medical College of Virginia, Box 48 MCV Station, Richmond, VA 23298-0001. 804/786-0494

August 15

Seminar on Geriatrics
 Place: Abingdon, VA
 Info: Ramona Miller, Ph.D., Program Coordinator, Office of CME, Quillen-Dishner College of Medicine, Johnson City, TN 37614. 615/929-6204

937

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lotte, 15 minutes to Lake Norman, Send C.V. to: Necip Ari, M.D., P.O. Box 656, Lincolnton 28092.

NEPHROLOGIST/CARDIOLOGIST - Growing practice in IM-Hypertension/Nephrology is seeking a partner/associate (IM-Nephrology/Cardiology). Location: Raleigh, North Carolina. Please send CV to: Charles Cook, M.D., M.P.H. P.O. Box 28145, Raleigh 27611.

WANTED-INFORMATION leading to JAMA issues, unbound, for the 1960s, 1970s plus 1980. Phone collect: 704/636-2466.

BLOWING ROCK: Family Practitioner to join two doctor practice in year round resort community. 28 bed JCAH approved hospital with associated nursing facility. Blowing Rock Medical Clinic, P.A., P.O. Box 8, Blowing Rock, 28605.

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INTERNIST with an interest in Gastroenterology needed to join a Cardiologist/Internist in a rural Louisiana town from July, 1987. Attractive first year salary, benefits, and early partnership. If interested, send CV to Manzoor H. Qazi, M.D., 1101A Port Arthur Terrace, Leesville, LA 71446.

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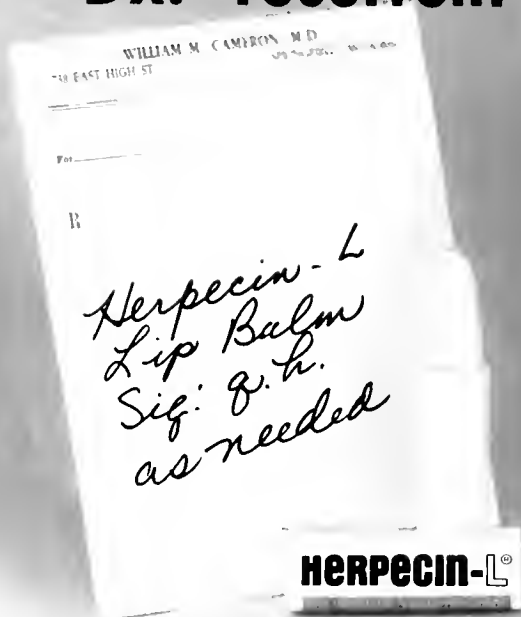
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Index to Advertisers

Allscrips Pharmaceuticals, Inc.	242	Keystone Management Services, Inc.	244
AMA	288	Knoll Pharmaceuticals	256a-b, 257
Ayerst Laboratories	248a-d	Medic Computer Systems	263
B & B X-Ray, Inc.	244	Medical Mutual Insurance Company of N.C.	262
Blue Cross and Blue Shield of N.C.	247	Medical Protective Company	245
Burroughs Wellcome Co.	264	National Staffing Services Corp.	241
Campbell Laboratories, Inc.	296	NCNB	246
Capital Placements	295	Reynolds & Reynolds	277
Carolina Manor	295	Roche Laboratories	260-261, 278-279, Cover 3-4
Charter Northridge Hospital	260	St. Albans Psychiatric Hospital	282
Communication Properties	255	Smith Kline & French	222a
Crumpton Company	Cover 2	The Upjohn Company	280a
Eli Lilly & Company	280b	U.S. Air Force	248
Focus: Healthcare	295	Winchester Surgical Supply Co.	246
Hinrichs Financial Group	256		

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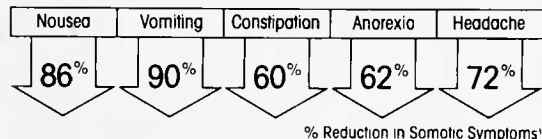
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Allergic: Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus.

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Gastrointestinal: Nausea, epigastric distress, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, black tongue.

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June 1987
Volume 48
Number 6

North Carolina Medical Journal

For Doctors and their Patients

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James P. Weaver, M.D.

**Breast
Imaging
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John T. Cuttino, Jr., M.D.

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North Carolina Medical Journal

FOR DOCTORS AND THEIR PATIENTS

Contents / June 1987, Volume 48, Number 6

Cover drawing by Ernest Craige, M.D.

SCIENTIFIC ARTICLES

- 303 Breast Imaging Techniques: Current Status *John T. Cuttino, Jr.*
307 Selective Endoscopic Treatment of Bronchogenic Carcinoma with the Carbon Dioxide Surgical Laser
James A. Koufman and R. Bradley Thomason III

EDITORIALS

- 312 Back to Chickens *James P. Weaver*
313 Learn and Live Health Museum *Elizabeth E. Gish*

FOR PATIENTS

- 317 Carbon Monoxide Poisoning in North Carolina *Lucy Fort and Patricia Griggs*
322 Which Medical Specialist for You?
The American Board of Medical Specialties

SOCIOECONOMICS

- 334 Implications for Fee-for-Service Practices Affiliated with Independent Practice Associations
John J. Aluisse, Don Bradley, and Bill Zelman

PHARMACOTHERAPY

- 341 Buspirone: Just Another Antianxiety Agent? *Timothy E. Poe*

BULLETIN BOARD

- 347 Letters to the Editor
349 Continuing Medical Education
350 Classified Advertisements
344 Instructions to Authors
352 Index to Advertisers

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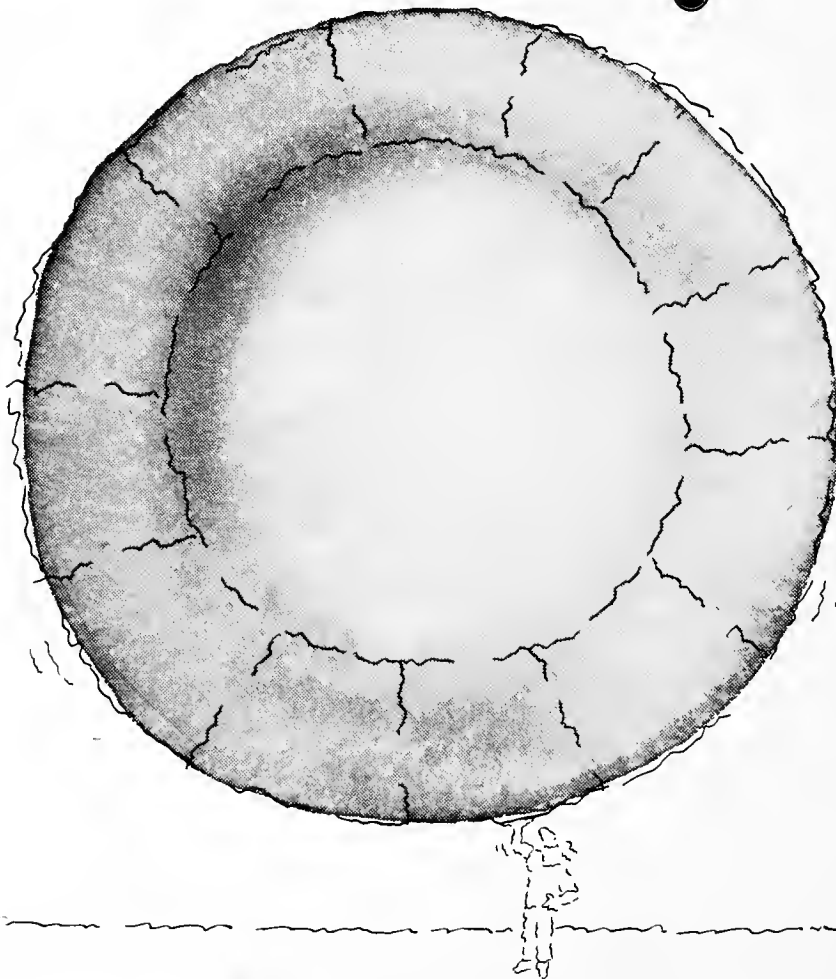
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Breast Imaging Techniques

Current Status

John T. Cuttino, Jr., M.D.

Breast cancer is now the most frequent cancer and leading cause of death in women, affecting one out of every 11 American women. The accurate and early detection of breast cancer is essential in controlling this disease.

It has now been well shown that mammography is useful in screening for breast cancer.¹⁻³ It is incumbent on the radiologist to provide the optimal technique and expertise in the performance and interpretation of mammograms.⁴

There are many current modalities to image the breast, including film-screen mammography, xeromammography, ultrasound mammography, diaphonography, thermography, computerized axial tomography, and magnetic resonance imaging. Let us briefly examine these modalities and then propose a rational approach to diagnosis.

Film Screen Mammography

Film-screen mammography has improved markedly in the past decade, in part because of improvements in film-screen systems. Currently in use are units dedicated to mammography. The most important breakthrough was the development of the low kilovoltage anode (Molybdenum) tube.

The state-of-the-art system employed today is a dedicated unit with built-in compression devices. This is combined with high-speed films and screens and grids. The result is a marked reduction in radiation dosage and improvement in contrast resolutions. In addition to these advantages, these radiographic systems are very reliable, with little "down time." Disadvantages are the restricted usability of the equipment, since it has few uses other than mammography, and greater technical difficulty in obtaining satisfactory images. Vigorous compression is necessary for the best images and it is necessary to view the radiographs with a hand magnifying lens to best see microcalcifications.⁴

From the Department of Radiology, University of North Carolina School of Medicine, Chapel Hill, 27514.

Xeromammography

Xeromammography uses an aluminum plate coated with selenium alloy sensitive to x-rays. The selenium plates are conditioned (charged). Incident x-rays dissipate areas of the charge and form an electrostatic latent image. This results in a "charge pattern" indicative of the actual x-ray image. The plate is developed by exposing the charged plate to a toner which adheres to the charges (proportionally). The image is transferred to a special paper and the paper is heated so the toner will adhere to it.

The xeroradiographic process results in less contrast in the image than with film-screen systems but produces an image with edge enhancement. This makes calcifications and certain lesions stand out more. The images can be made with any suitable radiographic equipment. In addition to these advantages, xeromammography enables better imaging of the chest wall, and eliminates the need for vigorous compression. Disadvantages include a higher frequency of repair (high "down time").⁴

There is little difference in accuracy of diagnosis between film-screen mammography and xeromammography. Both, when done properly by experienced, dedicated personnel and interpreted by equally experienced, dedicated radiologists, can give excellent results.⁵

Ultrasound

In the last five years, ultrasound mammography has been under development. It was hoped that ultrasound, being free of radiation risk and observable deleterious effects, would take its place as the screening modality of choice in breast diseases. Ultrasound can be used as a dedicated, automated

unit which produces "CT-like" images in the longitudinal and sagittal planes and records them on video tape. It can also be used as a hand-held small parts scanner (7.5-10 MHz. transducer) to evaluate the breasts. The accuracy of differentiating cystic from solid lesions approaches 100%. It can be useful in evaluating the "dense" breast which is difficult to evaluate by film-screen and xeromammography. This is of particular benefit in young premenopausal women who may normally have dense breasts and in whom one would like to reduce the radiation dose.

Advantages of Ultrasound mammography, then, are no radiation and accurate cyst/solid differentiation. Unfortunately, ultrasound has not been shown to be good in the screening situation and is not as good as film-screen or xeromammography.⁶ The dedicated ultrasound mammography equipment is costly and has virtually no other uses. Hand-held units can have many other uses and are useful as an adjunct to film-screen or xeromammography.

Diaphonography

Diaphonography, or transillumination, involves shining a light through the breast to illuminate its interior. Different tissues scatter light in different ways and these differences can be perceived by infrared-sensitive cameras. Currently fiberoptic hand-held light sources are used.

Advantages are much the same as with ultrasound: no radiation and no known hazard. Unfortunately, diaphonography has not been reliable in demonstrating small cancers and thus cannot be recommended as a screening tool.⁴

Thermography

Thermography is a technique where heat (as infrared radiation) can be pictured with specialized photographic techniques. Breast heat patterns are symmetrical except when altered by areas of altered metabolism, which appear as "hot" areas. Tumors that are rapidly growing have an increased blood supply and therefore appear as "hot spots" on the thermogram.

Unfortunately, almost all alterations from normal, including those from benign causes, appear as "hot spots." Thus the use of thermography is not recommended as a screening modality in evaluating breast diseases.²

Computerized Axial Tomography

CT is in the experimental stage for purposes of evaluating breast diseases. The computerized reconstruction of x-rays passing through the breasts permits evaluation of multiple images of the breasts.

Initial studies show that CT can be useful in detecting breast cancer, especially in dense breasts which are difficult to examine by mammography. Unfortunately, the technique requires relatively high x-ray exposures, contrast injection with its inherent dangers, and expensive equipment. Thus it is not to be recommended as a screening tool.⁷

Magnetic Resonance Imaging

MRI utilizes nuclear magnetic properties to generate an image in much the same way as CT uses x-rays. Currently under development and in the experimental stages, MRI can detect large breast cancers. It remains to be seen whether MRI will be able to improve upon film-screen mammography or xeromammography in detecting breast cancer.⁷

Summary

There are several diagnostic modalities available to image the breast. All have advantages and disadvantages. At the present time, screening mammography is best performed with film-screen mammography or xeromammography. Both of these modalities, when performed and interpreted properly, can detect "minimal breast cancer" before the lesions are clinically apparent.⁵ Ultrasound is useful as an adjunct to further evaluate a palpable lump or a lesion detected by mammography.⁶ Ultrasound and diaphonography are not recommended in the screening situation. Thermography has no role at all. CT and MRI are still in developmental stages and may be useful in specialized situations. ■

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GRAM-NEGATIVE AEROBES: *Enterobacter aerogenes*, *Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae* (including ampicillin-resistant strains), *H. parainfluenzae*, *Klebsiella* species (including *K. pneumoniae*), *Neisseria gonorrhoeae* (including penicillinase and nonpenicillinase-producing strains), *Neisseria meningitidis*, *Proteus mirabilis*, *Proteus vulgaris*, *Morganella morganii* and *Serratia marcescens*.

Note: Many strains of the above organisms that are multiply resistant to other antibiotics, e.g., penicillins, cephalosporins and aminoglycosides, are susceptible to ceftriaxone sodium.

Ceftriaxone is also active against many strains of *Pseudomonas aeruginosa*.

GRAM-POSITIVE AEROBES: *Staphylococcus aureus* (including penicillinase-producing strains) and *Staphylococcus epidermidis* (Note: methicillin-resistant *Staphylococcus* are resistant to cephalosporins, including ceftriaxone), *Streptococcus pyogenes* (Group A beta-hemolytic streptococci), *Streptococcus agalactiae* (Group B streptococci) and *Streptococcus pneumoniae* (Note: Most strains of enterococci, *Streptococcus faecalis* and Group D streptococci are resistant).

Ceftriaxone also demonstrates *in vitro* activity against the following microorganisms although the clinical significance is unknown:

GRAM-NEGATIVE AEROBES: *Citrobacter freundii*, *Citrobacter diversus*, *Providencia* species (including *Providencia rettgeri*), *Salmonella* species (including *S. typhi*), *Shigella* species and *Acinetobacter calcoaceticus*.

ANAEROBES: *Bacteroides* species, *Clostridium* species (Note: most strains of *C. difficile* are resistant).

SUSCEPTIBILITY TESTING: Standard susceptibility disk method. Quantitative methods that require measurement of zone diameters give the most precise estimate of antibiotic susceptibility. One such procedure (Bauer AW Kirby WMM, Sherris JC, Turck M: Antibiotic Susceptibility Testing by a Standardized Single Disk Method. *Am J Clin Pathol* 45:433-456, 1966; Standardized Disk Susceptibility Test. *Federal Register* 39:19182-19184, 1974; National Committee for Clinical Laboratory Standards, Approved Standard, ASM 2, Performance Standards for Antimicrobial Disk Susceptibility Tests, July 1975) has been recommended for use with disks to test susceptibility to ceftriaxone.

Laboratory results of the standardized single disk susceptibility test using a 30 mcg ceftriaxone disk should be interpreted according to the following criteria:

1. Susceptible organisms produce zones of 18 mm or greater indicating that the tested organism is likely to respond to therapy.
2. Organisms that produce zones of 14 to 17 mm are expected to be susceptible if a high degree of infection (not to exceed 4 gm per day) is used or if the infection is confined to tissues and fluids (e.g., urine), in which high antibiotic levels are attained.

3. Resistant organisms produce zones of 13 mm or less indicating that other therapy should be selected. Organisms should be tested with the ceftriaxone disk, since ceftriaxone has been shown by *in vitro* tests to be active against certain strains found resistant to cephalosporin class disks. Organisms having zones of less than 18 mm around the cephalosporin disk are not necessarily of intermediate susceptibility or resistant to ceftriaxone.

Standardized procedures require use of control organisms. The 30 mcg ceftriaxone disk should give zone diameters between 29 and 35 mm, 22 and 28 mm and 17 and 23 mm for the reference strains *E. coli* ATCC 25922, *S. aureus* ATCC 25923 and *P. aeruginosa* ATCC 27853, respectively.

DILUTION TECHNIQUES: Based on the pharmacokinetic profile of ceftriaxone, a bacterial isolate may be considered susceptible if the MIC value for ceftriaxone is not more than 16 mcg/ml. Organisms are considered resistant to ceftriaxone if the MIC is equal to or greater than 64 mcg/ml. Organisms having an MIC value of less than 64 mcg/ml, but greater than 16 mcg/ml, are expected to be susceptible if a high degree of infection (not to exceed 4 gm per day) is used or if the infection is confined to tissues and fluids (e.g., urine), in which high antibiotic levels are attained.

E. coli ATCC 25922, *S. aureus* ATCC 25923 and *P. aeruginosa* ATCC 27853 are also the recommended reference strains for controlling ceftriaxone dilution tests. Greater than 95% of MICs for the *E. coli* strain should fall within the range of 0.016 to 0.05 mcg/ml. The range for the *S. aureus* strain should be 1 to 2 mcg/ml, while for the *P. aeruginosa* strain the range should be 8 to 64 mcg/ml.

INDICATIONS AND USAGE: Rocephin is indicated for the treatment of the following infections when caused by susceptible organisms:

LOWER RESPIRATORY TRACT INFECTIONS caused by *Strep. pneumoniae*, *Streptococcus* species (including enterococci), *Staph. aureus*, *H. influenzae*, *H. parainfluenzae*, *Klebsiella* species (including *K. pneumoniae*), *E. coli*, *E. aerogenes*, *Proteus mirabilis* and *Serratia marcescens*.

SKIN AND SOFT TISSUE INFECTIONS caused by *Staph. aureus*, *Staph. epidermidis*, *Streptococcus* species (including enterococci), *E. cloacae*, *Klebsiella* species (including *K. pneumoniae*), *Proteus mirabilis* and *Pseudomonas aeruginosa*.

URINARY TRACT INFECTIONS (complicated and uncomplicated) caused by *E. coli*, *Proteus mirabilis*, *Proteus vulgaris*, *M. morganii* and *Klebsiella* species (including *K. pneumoniae*).

UNCOMPLICATED GONORRHEA (gonococcal urethritis and rectal) caused by *Neisseria gonorrhoeae*, including both penicillinase and nonpenicillinase-producing strains.

PELVIC INFLAMMATORY DISEASE caused by *N. gonorrhoeae*.

BACTERIAL SEPTICEMIA caused by *Staph. aureus*, *Strep. pneumoniae*, *E. coli*, *H. influenzae* and *K. pneumoniae*.

BONE AND JOINT INFECTIONS caused by *Staph. aureus*, *Strep. pneumoniae*, *Streptococcus* species (including enterococci), *E. coli*, *P. mirabilis*, *K. pneumoniae* and *Enterobacter* species.

INTRA-ABDOMINAL INFECTIONS caused by *E. coli* and *K. pneumoniae*.

MENINGITIS caused by *H. influenzae*, *N. meningitidis* and *Strep. pneumoniae*. Ceftriaxone has also been used successfully in a limited number of cases of meningitis and shunt infections caused by *Staph. epidermidis* and *E. coli*.

PROPHYLAXIS: The administration of a single dose of ceftriaxone preoperatively may reduce the incidence of postoperative infections in patients undergoing coronary artery bypass surgery.

Although ceftriaxone has been shown to have been as effective as cefazolin in the prevention of infection following coronary artery bypass surgery, no placebo-controlled trials have been conducted to evaluate any cephalosporin antibiotic in the prevention of infection following coronary artery bypass surgery.

SUSCEPTIBILITY TESTING: Before instituting treatment with Rocephin, appropriate specimens should be obtained for isolation of the causative organism and for determination of its susceptibility to the drug. Therapy may be instituted prior to obtaining results of susceptibility testing.

CONTRAINDICATIONS: Rocephin is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.

WARNINGS: BEFORE THERAPY WITH ROCEPHIN IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS OR OTHER DRUGS. THIS PRODUCT SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN SENSITIVE PATIENTS. ANTIBIOTICS SHOULD BE ADMINISTERED WITH CAUTION TO ANY PATIENT WHO HAS DEMONSTRATED SOME FORM OF ALLERGY PARTICULARLY TO DRUGS. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE THE USE OF SUBCUTANEOUS EPINEPHRINE AND OTHER EMERGENCY MEASURES.

Pseudomonas colitis has been reported with the use of cephalosporins (and other broad spectrum antibiotics); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use.

ROCEPHIN® (ceftriaxone sodium/Roche)

Treatment with broad spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis. Cholestyramine and colestipol resins have been shown to bind to the toxin *in vitro*. Mild cases of colitis respond to drug discontinuance alone. Moderate to severe cases should be managed with fluid, electrolyte and protein supplementation as indicated.

When the colitis is not relieved by drug discontinuance or when it is severe, oral vancomycin is the treatment of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should also be considered.

PRECAUTIONS: **GENERAL:** Although transients of BUN and serum creatinine have been observed, at the recommended dosages, the nephrotoxic potential of Rocephin is similar to that of other cephalosporins.

Ceftriaxone is excreted via both biliary and renal excretion (see Clinical Pharmacology). Therefore patients with renal failure normally require no adjustment in dosage when usual doses of Rocephin are administered but concentrations of drug in the serum should be monitored periodically. If evidence of accumulation exists, dosage should be decreased accordingly.

Dosage adjustments should not be necessary in patients with hepatic dysfunction; however in patients with both hepatic dysfunction and significant renal disease Rocephin dosage should not exceed 2 gm daily without close monitoring of serum concentrations.

Alterations in prothrombin times have occurred rarely in patients treated with Rocephin. Patients with impaired vitamin K synthesis or low vitamin K stores (e.g., chronic hepatic disease and malnutrition) may require monitoring of prothrombin time during Rocephin treatment. Vitamin K administration (10 mg weekly) may be necessary if the prothrombin time is prolonged before or during therapy. Prolonged use of Rocephin may result in overgrowth of non-susceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken. Rocephin should be prescribed with caution in individuals with a history of gastrointestinal disease, especially colitis.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Carcinogenesis: Considering the maximum duration of treatment and the class of the compound, carcinogenicity studies with ceftriaxone in animals have not been performed. The maximum duration of animal toxicity studies was six months. Mutagenesis: Genetic toxicology tests including the Ames test, a micronucleus test and a test for chromosomal aberrations in human lymphocytes cultured *in vitro* with ceftriaxone. Ceftriaxone showed no potential for mutagenic activity in these studies.

Impairment of Fertility: Fertility studies produced no impairment of fertility when given intravenously to rats at daily doses up to 586 mg/kg/day, approximately 20 times the recommended clinical dose of 2 gm/day.

PREGNANCY: Teratogenic Effects: Pregnancy Category B. Reproductive studies have been performed in mice and rats at doses up to 20 times the usual human dose and have no evidence of embryotoxicity, fetotoxicity or teratogenicity in primates. No embryotoxicity or teratogenicity was demonstrated at a dose approximately three times the human dose.

There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nonteratogenic Effects: In rats, in the Segment I (fertility and general reproduction) and Segment II (perinatal and postnatal) studies with intravenously administered ceftriaxone, no adverse effects were noted on various reproductive parameters during gestation and lactation, including postnatal growth, functional behavior and reproductive ability of the offspring, at doses of 586 mg/kg/day or less.

NURSING MOTHERS: Low concentrations of ceftriaxone are excreted in human milk. Caution should be exercised when Rocephin is administered to a nursing woman.

PEDIATRIC USE: Safety and effectiveness of Rocephin in neonates, infants and children have been established for the dosages described in the Dosage and Administration section.

ADVERSE REACTIONS: Rocephin is generally well tolerated in clinical trials. The following adverse reactions which were considered to be related to Rocephin therapy or of uncertain etiology, were observed:

LOCAL REACTIONS: Pain, induration or tenderness at the site of injection (1%). Less frequently reported (less than 1%) was phlebitis after IV administration.

HYPERSENSITIVITY: rash (1%). Less frequently reported (less than 1%) were pruritus, fever or chills.

HEMATOLOGIC: eosinophilia (6%), thrombocytopenia (5%) and leukopenia (2%). Less frequently reported (less than 1%) were anemia, neutropenia, lymphopenia, thrombocytopenia and prolongation of the prothrombin time.

GASTROINTESTINAL: diarrhea (2%). Less frequently reported (less than 1%) were nausea or vomiting and dyspepsia.

HEPATIC: elevations of SGOT (31%) or SGPT (33%). Less frequently reported (less than 1%) were elevations of alkaline phosphatase and bilirubin.

RENAL: elevations of the BUN (12%). Less frequently reported (less than 1%) were elevations of creatinine and the presence of casts in the urine.

CENTRAL NERVOUS SYSTEM: headache or dizziness were reported occasionally (less than 1%).

GENITOURINARY: moniliasis or vaginitis were reported occasionally (less than 1%).

MISCELLANEOUS: daphniosis and flushing were reported occasionally (less than 1%).

Other rarely observed adverse reactions (less than 0.1%) include leukocytosis, lymphocytosis, monocytosis, basophilia, a decrease in the prothrombin time, jaundice, glycosuria, hematuria, bronchospasm, serum sickness, abdominal pain, colitis, flatulence, dyspepsia, palpitations and epistaxis.

DOSEAGE AND ADMINISTRATION: Rocephin may be administered intravenously or intramuscularly. The usual adult daily dose is 1 to 2 gm given once a day or in equally divided doses twice a day depending on the type and severity of the infection. The usual daily dose should not exceed 4 grams.

For the treatment of serious musculoskeletal infections in children, other than meningitis, the recommended total daily dose is 50 to 75 mg/kg (not to exceed 2 grams) given in divided doses every 12 hours. Generally, Rocephin therapy should be continued for at least two days after the signs and symptoms of infection have disappeared. The usual duration is 4 to 14 days, in complicated infections longer therapy may be required.

In the treatment of meningitis, a daily dose of 100 mg/kg (not to exceed 4 grams), given in divided doses every 12 hours, should be administered with or without a loading dose of 75 mg/kg.

For the treatment of uncomplicated gonococcal infections, a single intramuscular dose of 250 mg is recommended.

For preoperative use (surgical prophylaxis), a single dose of 1 gm administered 1/2 to 2 hours before surgery is recommended.

When treating infections caused by *Streptococcus pyogenes* therapy should be continued for at least ten days.

No dosage adjustment is necessary for patients with impairment of renal or hepatic function; however blood levels should be monitored in patients with severe renal impairment (e.g., dialysis patients) and in patients with both renal and hepatic dysfunctions.

NOW SUPPLIED: Rocephin (ceftriaxone sodium/Roche) is supplied as a sterile crystalline powder in glass vials and piggyback bottles. The following packaging is available:

Vials containing 250 mg equivalent of ceftriaxone. Boxes of 10 (NDC 0004 1962 01).

Vials containing 500 mg equivalent of ceftriaxone. Boxes of 10 (NDC 0004 1963 01).

Vials containing 1 gm equivalent of ceftriaxone. Boxes of 10 (NDC 0004 1964 01).

Piggyback bottles containing 1 gm equivalent of ceftriaxone. Boxes of 10 (NDC 0004 1964 03).

Vials containing 2 gm equivalent of ceftriaxone. Boxes of 10 (NDC 0004 1965 01).

Piggyback bottles containing 2 gm equivalent of ceftriaxone. Boxes of 10 (NDC 0004 1965 03).

Bulk pharmacy containers, containing 10 gm equivalent of ceftriaxone. Boxes of 10 (NDC 0004 1971 01).

NOT FOR DIRECT ADMINISTRATION.

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Nutley, New Jersey 07110



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Selective Endoscopic Treatment of Bronchogenic Carcinoma with the Carbon Dioxide Surgical Laser

An Uncommon New Indication for Laser Bronchoscopy

James A. Koufman, M.D., and
R. Bradley Thomason III, M.D.

Carcinoma of the lung is the most common fatal cancer in men and is second only to breast cancer in women.¹ The stage at diagnosis ultimately determines the prognosis and potential for any given therapy. Although there are several modes of treatment available, excisional surgery forms the cornerstone of therapy and is the major potentially curative therapeutic option. In certain patients, however, such as those with bilateral lung tumors, major excision of lung parenchyma (e.g., pneumonectomy, lobectomy) may not be feasible. It is in such cases that laser surgery may prove to have an important role, and we present such a case here. The patient underwent a lobectomy of the left upper lobe and laser bronchoscopy of a nearly obstructing lesion of the right mainstem bronchus, with no evidence of recurrence of either carcinoma after two years.

The traditional role of endobronchial laser surgery, i.e., mainly to debulk obstructing tumor recurrences as a purely palliative tool, is challenged by the outcome in this case. Indeed in selected cases, when no other options seem feasible, bronchoscopic laser surgery may offer a potential cure.

Case Report

Two years after a normal chest x-ray, a 59-year-old caucasian man was admitted with complaints of progressive dyspnea for one year, some hemoptysis, and a five-pound weight loss over the previous six months. The past medical history revealed borderline hypertension, arthritis, and

chronic obstructive pulmonary disease. He was a 60-pack-year cigarette smoker and had been an alcohol abuser in the past.

Examination of the chest revealed clear breath sounds bilaterally without wheezes or crackles. The chest x-rays showed a solitary nodule with smooth rounded borders in the left upper lobe; the lesion measured $32 \times 39 \times 36$ mm. Serum chemistry studies and a complete blood cell count were normal. Bone scans and a liver/spleen scan showed no abnormalities. Split lung perfusion tests showed equal function bilaterally. Pulmonary function tests showed an FEV₁ of two liters. A computed tomographic scan of the chest showed the pulmonary nodule in the left upper lobe but no evidence of hilar adenopathy or additional lesions. However, fiberoptic bronchoscopy showed a second lesion, described as "a large exophytic pedunculated mass in the right mainstem bronchus at the orifice of the right upper lobe bronchus with approximately 50% obstruction of the right mainstem." Biopsy of this lesion showed poorly differentiated squamous cell carcinoma. During repeat bronchoscopy several days later to evaluate the feasibility of sleeve resection of the right mainstem lesion, percutaneous needle biopsy of the left upper lobe lesion showed it, also, to be poorly differentiated squamous cell carcinoma.

These findings presented a difficult therapeutic dilemma. Could the patient tolerate bilateral upper lobectomies and sleeve resection of the right mainstem bronchus? The morbidity and mortality of this approach were considered too great. Could a left upper lobectomy be performed, temporarily leaving the right endobronchial lesion for staged resection? The risk of complete airway obstruction and hemoptysis seemed to preclude this option. Should both lesions simply be treated with chemotherapy and/or radiation therapy, although the cure rate from these options is very low? What would be the safest and most effective therapy for this patient with bilateral carcinoma of the lung?

From the Sections on Otolaryngology and General Surgery, Department of Surgery, Wake Forest University Medical Center, Winston-Salem 27103.

Treatment

We chose to perform bronchoscopic laser surgery of the right mainstem lesion to prevent further bleeding and obstruction, and then to proceed with the left upper lobectomy. At a later date the patient could be reoperated upon for the right endobronchial lesion.

Rigid bronchoscopic laser ablation of the right mainstem lesion, using the carbon dioxide laser under general anesthesia, was performed without complication. The patient underwent left upper lobectomy four days later. Eleven bronchopulmonary lymph nodes were examined histopathologically, and all 11 as well as the resection margins were free of tumor. The postoperative course was unremarkable and the patient was discharged from the hospital on the ninth postoperative day.

Repeat bronchoscopy was performed at one, three, five, nine, and 24 months postoperatively. At one month, the previously noted exophytic right-sided mass appeared as a flat plaque-like lesion 8 mm in diameter. There was no gross evidence of tumor invasion through the bronchus. This lesion was presumed to be the base of the previously treated lesion, and was again ablated with the CO₂ laser.

At three months, there was a small amount of granulation tissue at the ablation site, and it was removed with the laser. Histopathologic examination of the specimen showed granulation tissue predominantly with a single focus of squamous cell carcinoma. At five months, a 10 mm area of leukoplakia was noted in the same location and was excised with the CO₂ laser; this time there was no histologic evidence of carcinoma. At nine months a small area of granulation tissue was excised with the laser, and again showed no histologic evidence of carcinoma.

At 24 months the mucosa was pink, well healed, and without evidence of tumor; bronchial washings were negative for carcinoma. Chest x-rays showed changes consistent with the previous lobectomy but no evidence of carcinoma. We continue to follow this patient.

Discussion

Laser bronchoscopy is a relatively new therapeutic modality, performed primarily with two wavelength lasers, the Neodymium:Yttrium-Aluminum-Garnet (Nd:YAG) and the carbon dioxide (CO₂) lasers. The CO₂ laser provides a visible and predictable depth of penetration and serves well as a "laser scalpel."² Hemostasis, on the other hand, is only fair. The Nd:YAG laser has a greater though somewhat unpredictable depth of penetration. It has better hemostatic properties, and has a further advantage in that its energy can be delivered through a fiberoptic source.³

In actuality, the two lasers provide much the same clinical outcome. Both wavelengths of laser energy can be delivered via large-bore rigid bronchoscopes, ideal in cases of hemoptysis or with obstruction of both lungs wherein rapid

clearing of smoke, blood, and tumor debris is required.³ For all such cases, general anesthesia is recommended. The rigid bronchoscope also offers the advantages of superior optics, more effective and rapid tumor vaporization, and a reduced risk of endobronchial combustion.^{3,4} On the other hand, the flexible bronchoscope and the Nd:YAG laser can often be used without general anesthesia and can provide the visualization necessary to approach "hard to reach" lesions. Highly vascular lesions are best treated with the Nd:YAG laser.³

In the early clinical reports of Nd:YAG laser bronchoscopic treatment of pulmonary cancers, only terminally ill patients for whom the usual treatment modalities had been exhausted were considered.³ Later, laser therapy was utilized earlier in the treatment course of the disease, in conjunction with radiation or chemotherapy. These, however, were still primarily palliative treatments. As the technology and operator skill improved, a wider scope of therapeutic potential for laser surgery was realized, yet the most common indications for laser treatment have remained dyspnea due to airway obstruction, post-obstructive pneumonia or atelectasis, and hemoptysis.^{2,5-7} Current clinical reports have stated that continued and repeated use of the Nd:YAG laser for *palliative* treatment of obstructing malignant lesions is indicated, and that laser therapy should be used in conjunction with radiation therapy if surgery is not the primary treatment modality for the patient.^{8,9}

Thus there are no guidelines for primary treatment of endobronchial carcinoma with the surgical laser. There have been reports related to hematoporphyrin derivative (HpD) laser and photoradiation therapy (PRT) being used for detection and even cure of small superficial squamous cell carcinomas of the central tracheobronchial tree, but their application is limited to mucosal disease.^{10,11} Perhaps HpD and PRT are most valuable as a tumor-specific marker for the early diagnosis of bronchogenic carcinoma.^{12,13}

Reported complications of laser bronchoscopy include hemorrhage, pneumothorax, and respiratory distress secondary to free tumor causing bronchial obstruction.^{2,4,9} Massive hemorrhage has led to death in several patients,^{2,7} particularly with the Nd:YAG laser, since the depth of penetration is more difficult to predict. Other reported perioperative complications include cardiovascular shock, cardiac dysrhythmias and arrest, hypoxemia, and myocardial infarction.³ Additional shortcomings of laser therapy include the relative inability to treat deep lobar or segmental lesions and the relatively short duration of palliation after treatment of many obstructing lesions.⁹

The case presented here suggests that selected patients with endobronchial lesions, especially those with multicentric or bilateral disease, may be candidates for endoscopic laser resection of one or more of the endobronchial lesions. Of importance in these cases is the need for repeated endoscopic evaluation and therapy. (In this case, for example, three treatments over a three-month period were needed before the tumor was eradicated.)

Obviously, the exophytic nature of the lesion in this patient and its failure to penetrate deeply into the bronchial wall or to metastasize suggest that although it nearly obstructed the bronchus, it was still a relatively early lesion. The case presented here is not a commonly encountered clinical situation. While surgical resection remains the primary curative mode of therapy, we believe that laser bronchoscopy for cure can and should be considered in selected cases. ■

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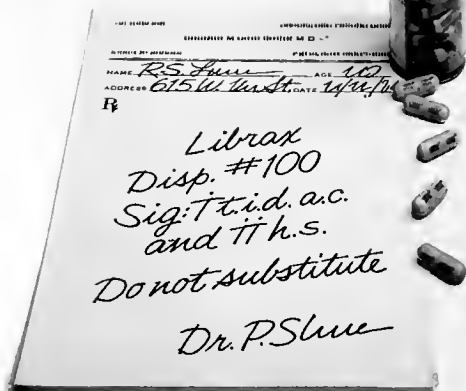
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Indications: Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the indications as follows:
"Possibly" effective: as adjunctive therapy in the treatment of peptic ulcer and in the treatment of the irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis.
Final classification of the less-than-effective indications requires further investigation.

Contraindications: Glaucoma; prostatic hypertrophy, benign bladder neck obstruction; hypersensitivity to chlordiazepoxide HCl and/or clidinium Br.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants, and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Physical and psychological dependence rarely reported on recommended doses, but use caution in administering Librium[®] (chlordiazepoxide HCl/Roche) to known addiction-prone individuals or those who might increase dosage; withdrawal symptoms (including convulsions) reported following discontinuation of the drug.

Usage in Pregnancy: Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy. Advise patients to discuss therapy if they intend to or do become pregnant.

As with all anticholinergics, inhibition of lactation may occur.
Precautions: In elderly and debilitated, limit dosage to smallest effective amount to preclude ataxia, oversedation, confusion (no more than 2 capsules/day initially; increase gradually as needed and tolerated). Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider pharmacology of agents, particularly potentiating drugs such as MAO inhibitors, phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions reported in psychiatric patients. Employ usual precautions in treating anxiety states with evidence of impending depression; suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation reported very rarely in patients receiving the drug and oral anticoagulants; causal relationship not established.

Adverse Reactions: No side effects or manifestations not seen with either compound alone reported with Librax. When chlordiazepoxide HCl is used alone, drowsiness, ataxia, confusion may occur, especially in elderly and debilitated; avoidable in most cases by proper dosage adjustment, but also occasionally observed at lower dosage ranges. Syncope reported in a few instances. Also encountered: isolated instances of skin eruptions, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased libido—all infrequent, generally controlled with dosage reduction; changes in EEG patterns may appear during and after treatment; blood dyscrasias (including agranulocytosis), jaundice, hepatic dysfunction reported occasionally with chlordiazepoxide HCl, making periodic blood counts and liver function tests advisable during protracted therapy. Adverse effects reported with Librax typical of anticholinergic agents, i.e., dryness of mouth, blurring of vision, urinary hesitancy, constipation. Constipation has occurred most often when Librax therapy is combined with other spasmolytics and/or low residue diets.



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*Librax has been evaluated as possibly effective as adjunctive therapy in the treatment of peptic ulcer and the irritable bowel syndrome.

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Back to Chickens

James P. Weaver, M.D.

A good idea is a good idea. Those things which have seen the test of time must be remembered as we search for answers to our ever-challenging professional dilemmas. Recently issued Medicare "guidelines" for physician charges have raised awareness of the continued threat of government control, and for the sake of our profession, I feel it is time for organized medicine to resurrect one of our ancient but still functional traditions: let us go back to chickens.

A general concept that the Feds have come up with is "MAAC," or the "maximum allowable actual charge." In attempting to keep the lid on health care costs, the government has clarified in their December 1986 mailing our "allowable charges" with the following language: "If the physician's 1984 base period charge (or 1986 average actual charge, if lower) is equal to or greater than 115% of the 1987 prevailing charge for non-participating physicians, the MAAC is equal to 101% of the 1984 base period charge." I have taken the time to reproduce certain critical quotations from this mailing so that the clarity is not lost in my translation. I have a terrible time understanding these "guidelines," but after all, I'm not an accountant, just a surgeon.

Chicken Feed

As surgeons are known for taking the simple sure approach, I suggest we begin charging in "chickens," and forget Medicare. Why?

It will remove us from the ever-tightening noose of the Medicare system. It is plain that the basis of the dialogue between the Government and Medicine, despite public avoidance of the topic, is money. Physicians want more, government wants to spend less, and patients want the most for the least. It seems evident that the "incentives" to "participate" will only get stronger. I see no reason for the government to change direction now or in the future, and I expect the "pressure" to increase.

Chickens are our only answer. If we continue the present dialogue we will only be losers. If we step out of the game by going to chickens, the worst that can happen is physicians will gain four or five years while the bureaucrats convert their system to ours and restart the dialogue.

Can you imagine, "Your charges for the year 1996 will be based on the conversion factor: three chickens maximum charge per office visit (based on chicken/\$1.22, 1992 Chicken Index). If the average charge for that year is equal to 1/2 of 1% of the mean Chicken Index for the preceeding year minus the projected chicken crop for 1997, you may charge the least of your MCCC (Mean Client Chicken Charge) or the PCCC (Prevailing Client Chicken Charge)."

A second advantage is the potential elimination of the conflict between cognitive and procedural reimbursement. The ease with which dollars can be transferred has inflated the procedural charges far beyond the cognitive. The simple leveling effect of storage space should temper the charges for such notorious procedures as cardiac transplants, liver transplants, and cataracts; there will simply be no place to store the "fee." Consequently, the "medical types" will raise their charges just a bit, and the "surgical types" will be forced to drop theirs and in effect narrow the "Chicken Gap."

The Way to a Physician's Heart

Another important, gastronomic, benefit will be the potential strengthening of the ever important physician-patient relationship. Receiving a chicken casserole from the town gourmet might not be so bad. It has to beat having a patient abscond with your \$55 check from Medicare because you didn't accept assignment.

Just the thought that there might be a glimmer of hope to answer the "Medicare Pressure" has made my day. Maybe physicians should get together and organize this approach, but the Federal Trade Commission says that we're not allowed to organize anymore. Anyway, if we do try it, and if the Feds catch up with us, we can always switch to pigs or sheep to gain another two or three years' respite.

Yes, things do look brighter, but I guess I shouldn't count my chickens before they're hatched! ■

From Durham Clinic, P.A., 1830 Hillandale Rd., Durham 27705

Learn and Live Health Museum

Elizabeth E. Gish

This article will serve as an introduction to the recently opened Learn and Live Health Museum in Salisbury. The completion of this ambitious project in August, 1986, represents the culmination of an intensive seven-year volunteer effort to develop a permanent health museum for this community.

The Rowan County Medical Society and Auxiliary's leadership spearheaded the founding of Rowan Learn and Live, Inc., in 1982 with their initial commitment and financial support in the amount of \$2,000. During the capital campaign to raise \$151,000, the contributions from the medical community alone totalled over \$35,000. The average gift from each physician was approximately \$800.

The project's Board of Directors worked cooperatively with the school systems, with health educators, pharmacists, dentists, and other health professionals, and with numerous civic organizations to develop a comprehensive health museum. Surveys determined specific needs, and professional design consultants were employed to design "hands-on" exhibitry and a dynamic and colorful museum.

This project may be of special interest to NCMJ readers in that the idea had its inception when I attended a 1978 American Medical Association Auxiliary National Leadership Confluence in Chicago, as President-Elect from Rowan County, NC. The projects, seminars on national issues, tapes, literature and other information shared at this meeting were very stimulating to me personally, and this annual meeting affords local auxiliary leadership tremendous growth opportunities and presents excellent ideas for implementing effective programs on a local level.

Additionally, as North Carolina's State Doctors' Day Chairman, I reviewed many reports and became aware of many worthwhile medical auxiliary projects in North Carolina. Certainly, the potential for productivity in all the AMA Auxiliaries is limited only by our energies.

The Rowan County Medical Auxiliary has a relatively small membership (less than 100), but armed with our main objective "to interpret the aims of the medical profession

to other organizations interested in the promotion of health education," and knowing that over 85% of medical auxiliary members nationally are educated in health related fields, we determined to build a permanent health museum. Our hope was for continuing opportunities to learn about the human body, its functions and processes, to encourage the formulation of healthy lifestyles and attitudes, to help prevent disease and to provide a very visible and lasting gift to the citizens of this community.

The success of the Rowan County Medical Society and Auxiliary-sponsored Project H.E.L.P. (Healthful Education for Little People) also helped inspire the establishment of Learn and Live Health Museum.

The Learn and Live Museum is a dynamic, colorful, educational, and entertaining exhibit hall that appeals to a wide audience, from pre-school groups to senior citizens. "Hands-On" models allow the very young to better understand the amazing human body, and detailed script was written to offer detailed information for the college-level visitors and all who are inquisitive and want to learn. Visitors see exhibits called the "colors of health" and learn how patterns of healthy living can assure a "rainbow life."

The unique aspect of the Learn and Live Museum is the personal involvement of both the medical society and auxiliary members over the past several years. Together we made a commitment to develop one of the most comprehensive health museums in North Carolina. We have succeeded! Members wrote the script, acted as consultants on graphics, anatomical and physiology models, wallpapered, gave museum tours, sold T-shirts, made presentations to community groups, proofread museum text, labelled detailed German models, hauled off trash, and designed signs. Over 15,000 hours of volunteer time have gone into the completion of this museum. To date we have no salaried administrator.

The facility of Learn and Live is valued at over \$200,000. Countless community contractors, building supply companies, and services were donated to keep the costs under budget. \$151,000 was a large sum for this community to raise in a year's time. Donations were given in support of "an idea." It was many months before supporters could see the results of their gifts. The grass-roots support from Learn

From the President, Learn and Live, Inc., and Health Education Chairman, Rowan County Medical Society Auxiliary, District 9, Salisbury 28144.

and Live memberships, funding from several foundations, and support from local corporations and civic groups made our "rainbow dream" a reality.

I have been President of Learn and Live since 1982, and Health Education Chairman of the Rowan Medical Auxiliary for the past several years. I would like to thank publicly all of the members of our local medical society and auxiliary and all of the other countless supporters in this community for their genuine dedication to see a dream become a reality. Together we are proud to see that determination, hard work, and belief in a worthwhile project provided the labor and the professional leadership in this community to build a lasting and meaningful museum with exhibits and programs to promote the health of all the citizens in this community.

I think this project exemplifies "teamwork" and an outstanding cooperative effort between the Rowan Medical Society and Auxiliary in Salisbury, North Carolina. During my term as president of our auxiliary, the state theme was

"Making and Mending Healthful Lifestyles." It has taken seven years to build Learn and Live, but the museum provides every visitor an opportunity to develop a healthier lifestyle.

Learn and Live is a member of the American Association of Museums and the North Carolina Museum Council, and is listed in the current guide to NC science centers prepared by the NC Academy of Sciences and the NC School of Science and Mathematics.

Since we opened the doors in August 1986, over 3,000 visitors have toured the health museum free of charge. Groups have included school classes, Scouts, the American Association of University Women, the Adult Retarded Citizens, and the Trainably Mentally Handicapped.

All exhibits are designed to accommodate the handicapped with a ramp within the two-level exhibit hall, and all exhibits have elements enabling the visually impaired and hearing impaired to use them. ■

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Reactions Common to Both Products: **Contraindications:** These products are contraindicated in those individuals who have shown hypersensitivity to any of the components, and in herpes simplex, vaccinia and varicella. **Warnings:** As with other antibiotic preparations, prolonged treatment may result in overgrowth of nonsusceptible organisms and fungi. If the infection is not improved after one week, cultures and susceptibility tests should be repeated to verify the identity of the organism and to determine whether therapy should be changed. When using neomycin-containing products to control secondary infection in the chronic dermatoses, such as chronic otitis externa, it should be borne in mind that the skin in these conditions is more liable than is normal skin to become sensitized to many substances, including neomycin. The manifestation of sensitization to neomycin is usually a low grade reddening with swelling, dry scaling and itching; it may be manifest simply as a failure to heal. During long-term use of neomycin-containing products, periodic examination for such signs is advisable and the patient should be told to discontinue the product if they are observed. These symptoms regress quickly on withdrawing the medication. Neomycin-containing applications should be avoided for that patient thereafter. **Precautions:** If sensitization or irritation occurs, medication should be discontinued promptly. Patients who prefer to warm the medication before using should be cautioned against heating the solution above body temperature in order to avoid loss of potency. Treatment should not be continued for longer than ten days. Allergic cross-reactions may occur which could prevent the use of any or all the following antibiotics for the treatment of future infections: kanamycin, paromomycin, streptomycin, and possibly gentamicin. **Adverse Reactions:** Neomycin is a not uncommon cutaneous sensitizer. There are articles in the current literature that indicate an increase in the prevalence of persons sensitive to neomycin.

*Caution: If perforation of the eardrum exists, specify Cortisporin Otic Suspension (this drug should be used with care in cases of perforated eardrum).

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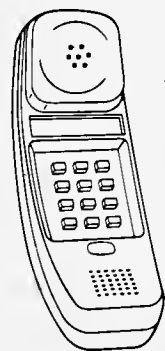
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ranitidine HCl/Glaxo 150 mg tablets

EFFECTIVE MAINTENANCE THERAPY

for healed duodenal ulcer patients

See last page for references and
Brief Summary of Product Information.

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In two randomized, double-blind, and well-controlled clinical trials, ZANTAC 150 mg h.s. significantly superior to cimetidine 400 mg h.s. for maintenance therapy in healed duodenal ulcers.

Percent of patients with observed duodenal ulcer recurrence

		0-4 months	0-8 months	0-12 months	No. patients
USA ¹	ranitidine 150 mg h.s.	9%	14%*	16%†	60
	cimetidine 400 mg h.s.	23%	34%	43%	66
UK, Ireland, Australia ²	ranitidine 150 mg h.s.	8%‡	14%‡	23%‡	243
	cimetidine 400 mg h.s.	21%	34%	37%	241

*p=0.02

†p=0.01

‡p<0.004

‡=life-table estimates

All patients were permitted prn antacids for relief of pain.

These two trials used the currently recommended dosing regimen of cimetidine (400 mg h.s.) and ranitidine (150 mg h.s.). A comparison of other dosing regimens has not been studied.

The studied dosing regimens are not equivalent with respect to the degree and duration of acid suppression or suppression of nocturnal acid.

The superiority of ranitidine over cimetidine in these trials indicates that the dosing regimen currently recommended for cimetidine is less likely to be as successful in maintenance therapy.

Convenient once-a-night dose with a
low incidence of side effects³

Headache, sometimes severe, seems to be related to ranitidine administration. Other side effects have been reported; for a complete listing, see the ADVERSE REACTIONS section in the Brief Summary.

No significant interference with the hepatic cytochrome
P-450 enzyme system at recommended doses

ZANTAC 150 mg has no significant drug interactions with theophylline, phenytoin, or warfarin. The bioavailability of certain medications whose absorption is dependent on a low gastric pH may be altered when ZANTAC or other medications that decrease gastric acidity are administered.

Zantac[®] 150
ranitidine HCl/Glaxo 150 mg tablets

One tablet at bedtime
for maintenance

See next page for references and
Brief Summary of Product Information.

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Zantac 150

ranitidine HCl/Glaxo 150 mg tablets

One tablet at bedtime for maintenance therapy
in healed duodenal ulcer patients

References:

1. Silvis SE, Griffin J, Hardin R, et al: Final report on the United States multicenter trial comparing ranitidine to cimetidine as maintenance therapy following healing of duodenal ulcer. *J Clin Gastroenterol* 1985;7(6):482-487.
2. Gough KR, Korman MG, Bardhan KD, et al: Ranitidine and cimetidine in prevention of duodenal ulcer relapse: A double-blind, randomised, multicentre, comparative trial. *Lancet* 1984;ii:659-662.
3. Data available on request, Glaxo Inc.

ZANTAC® 150 Tablets
(ranitidine hydrochloride)
ZANTAC® 300 Tablets
(ranitidine hydrochloride)

BRIEF SUMMARY OF PRODUCT INFORMATION

The following is a brief summary only. Before prescribing, see complete prescribing information in ZANTAC® product labeling.

INDICATIONS AND USAGE: ZANTAC® is indicated in

1. Short-term treatment of **active duodenal ulcer**. Most patients heal within four weeks.
2. **Maintenance therapy** for duodenal ulcer patients at reduced dosage after healing of acute ulcers.
3. The treatment of **pathological hypersecretory conditions** (eg, Zollinger-Ellison syndrome and systemic mastocytosis).
4. Short-term treatment of **active, benign gastric ulcer**. Most patients heal within six weeks and the usefulness of further treatment has not been demonstrated.
5. Treatment of **gastroesophageal reflux disease (GERD)**. Symptomatic relief commonly occurs within one or two weeks after starting therapy and is maintained throughout a six-week course of therapy.

In active duodenal ulcer, active, benign gastric ulcer; hypersecretory states, and GERD, concomitant antacids should be given as needed for relief of pain.

CONTRAINDICATIONS: ZANTAC® is contraindicated for patients known to have hypersensitivity to the drug.

PRECAUTIONS: Symptomatic response to ZANTAC® therapy does not preclude the presence of gastric malignancy.

Since ZANTAC® is excreted primarily by the kidney, dosage should be adjusted in patients with impaired renal function (see **DOSAGE AND ADMINISTRATION**). Caution should be observed in patients with hepatic dysfunction since ZANTAC® is metabolized in the liver.

False-positive tests for urine protein with Multistix® may occur during ZANTAC® therapy, and therefore testing with sulfosalicylic acid is recommended.

Although recommended doses of ZANTAC® do not inhibit the action of cytochrome P-450 enzymes in the liver, there have been isolated reports of drug interactions which suggest that ZANTAC® may affect the bioavailability of certain drugs by some mechanism as yet unidentified (eg, a pH-dependent effect on absorption or a change in volume of distribution).

Lack of experience to date precludes recommending ZANTAC® for use in children or pregnant patients. Since ZANTAC® is secreted in human milk, caution should be exercised when administered to a nursing mother.

ADVERSE REACTIONS: Headache, sometimes severe, seems to be related to ZANTAC® administration. Constipation, diarrhea, nausea/vomiting, and abdominal discomfort/pain have been reported. There have been rare reports of malaise, dizziness, somnolence, insomnia, vertigo, tachycardia, bradycardia, premature ventricular beats, and arthralgias. Rare cases of reversible mental confusion, agitation, depression, and hallucinations have been reported, predominantly in severely ill elderly patients.

In normal volunteers, SGPT values were increased to at least

twice the pretreatment levels in 6 of 12 subjects receiving 100 mg qid IV for seven days, and in 4 of 24 subjects receiving 50 mg qid for five days. With oral administration there have been occasional reports of reversible hepatitis, hepatocellular or hepatocanalicular or mixed, with or without jaundice.

There have been rare reports of reversible leukopenia, granulocytopenia, thrombocytopenia, and pancytopenia.

Although controlled studies have shown no antiandrogenic activity, occasional cases of gynecomastia, impotence, and loss of libido have been reported in male patients receiving ZANTAC®, but the incidence did not differ from that in the general population.

Incidents of rash, including rare cases suggestive of mild erythema multiforme, and, rarely, alopecia, have been reported, as well as rare cases of hypersensitivity reactions (eg, bronchospasm, fever, rash, eosinophilia) and small increases in serum creatinine.

OVERDOSAGE: Information concerning possible overdose and its treatment appears in the full prescribing information.

DOSAGE AND ADMINISTRATION Active Duodenal Ulcer: The current recommended adult oral dosage is 150 mg twice daily. An alternate dosage of 300 mg once daily at bedtime can be used for patients in whom dosing convenience is important. The advantages of one treatment regimen compared to the other in a particular patient population have yet to be demonstrated.

Maintenance Therapy: The current recommended adult oral dosage is 150 mg at bedtime.

Pathological Hypersecretory Conditions (such as Zollinger-Ellison Syndrome): The current recommended adult oral dosage is 150 mg twice a day. In some patients it may be necessary to administer ZANTAC 150 mg doses more frequently. Doses should be adjusted to individual patient needs, and should continue as long as clinically indicated. Doses up to 6 g/day have been employed in patients with severe disease.

Benign Gastric Ulcer: The current recommended adult oral dosage is 150 mg twice a day.

GERD: The current recommended adult oral dosage is 150 mg twice a day.

Dosage Adjustment for Patients with Impaired Renal Function: On the basis of experience with a group of subjects with severely impaired renal function treated with ZANTAC®, the recommended dosage in patients with a creatinine clearance less than 50 ml/min is 150 mg every 24 hours. Should the patient's condition require, the frequency of dosing may be increased to every 12 hours or even further with caution. Hemodialysis reduces the level of circulating ranitidine. Ideally, the dosage schedule should be adjusted so that the timing of a scheduled dose coincides with the end of hemodialysis.

NOW SUPPLIED: ZANTAC® 300 Tablets (ranitidine hydrochloride equivalent to 300 mg of ranitidine) are yellow, capsule shaped tablets embossed with "ZANTAC 300" on one side and "Glaxo" on the other. They are available in bottles of 30 (NOC 0173-0393-40) and unit dose packs of 100 tablets (NOC 0173-0393-47).

ZANTAC® 150 Tablets (ranitidine hydrochloride equivalent to 150 mg of ranitidine) are white tablets embossed with "ZANTAC 150" on one side and "Glaxo" on the other. They are available in bottles of 60 tablets (NOC 0173-0344-42) and unit dose packs of 100 tablets (NOC 0173-0344-47).

Store between 15° and 30°C (59° and 86°F) in a dry place. Protect from light. Replace cap securely after each opening.

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Carbon Monoxide Poisoning in North Carolina

LUCY FORT, R.N., AND PATRICIA GRIGGS, R.N.

It was a cold February morning when two brothers, 12 and 14 years old, stayed in a car with the engine running while their mother went into a house for a short visit. "Fifteen minutes" later when she returned, she found her 14-year-old son confused and dizzy, and her 12-year-old son dead. This child was one of 793 North Carolinians who died from carbon monoxide (CO) poisoning during the years 1972-1985.

Of the 793 deaths, 442 (56%) were from suicide; four (.5%) were from homicide; 14 (2%) were questionable as suicide or accidental death; and 333 (42%) were accidental (table 1). We review the accidental deaths (tables 2, 3, and 4),¹ and discuss fire fighters as a high-risk group for such accidents.

Carbon monoxide is a colorless, odorless, tasteless, poisonous gas formed by incomplete combustion of organic or carbonaceous material. It is present in the air we breathe and only becomes a threat to our life when it reaches high concentrations in confined spaces. Lower concentrations also can cause harmful effects, if exposure occurs over a long period of time. Each year in the United

States, CO poisoning accounts for approximately 3,500 accidental or suicidal deaths.

Our review highlights the significance of CO intoxication as a common cause of accidental death in North Carolina. Moreover, case examples from the review demonstrate that CO intoxication in living persons can go undiagnosed because the symptoms of the exposure are not specific. The lesson for emergency service personnel is that they may be the only professionals who have the opportunity to view the circumstances of the exposure. Careful observation leading to a suspicion of CO exposure by rescue personnel may therefore provide the victim with his or her only chance of appropriate treatment and possible survival.

Two broad categories of CO exposure accidents were defined by the presence or absence of the involvement of an automobile. Two hundred seventy-six (83%) of the accidental deaths were associated with motor vehicles — the most common circumstance of CO exposure. Most of these, 173, occurred in vehicles parked with the motor running. Forty-four of these cases involved couples in parked vehicles; in three cases, one of the two persons survived while the companion died.

Most of the vehicles were found to have severely defective exhaust systems. Many were missing tail pipes so that the exhaust system ended just beneath the rear seat. Also, frequently, holes were discovered drilled into the trunk and rear compartment for stereo speakers or

From The North Carolina Memorial Hospital at the University of North Carolina at Chapel Hill, and Orange County Emergency Services, 106 E. Margaret Lane, Hillsborough 27278.

Table 1

**Fatal Carbon Monoxide Poisoning in North Carolina
1972-1985**

<i>Manner of Death</i>	
Suicide	442 (56%)
Accident	333 (42%)
Homicide	4 (0.5%)
Unknown	14 (2%)
Total Deaths	793

other equipment, or holes were observed in the floor boards from rust and wear. As with the two children in the parked car, many of the situations involved very short periods of exposure.

Motor Vehicle Exposure Cases

In November, a one-year-old was left sleeping in his father's pickup truck. The engine and heater were left running. After cutting wood for approximately 30 minutes within sight of the truck, the father checked on his son. CO had entered through the truck's rusty floorboard and the baby was dead.

On another cold evening, a father and his 13-month-old son had driven in a pickup truck to the wife's work place. They arrived around 8:30 and sat in the truck with the engine running to keep warm. The wife left work at 9:45 and found her husband and child in the truck unresponsive. The father recovered, but efforts to resuscitate the child failed.

In another case, a 19-year-old man arrived early for work. He sat in his "old Nash" waiting for his supervisor to arrive to unlock the garage doors. When the supervisor arrived, he found the young man in the Nash dead. The engine was still running, the doors were unlocked, and the heater and radio were on. Multiple holes were evident in the muffler on the automobile.

In spite of years of experience with this problem and a general understanding that sitting in a parked vehicle with the engine running is dangerous, these accidents continue to occur. For rescuers, any confused or unconscious person in a vehicle should be suspected of having CO exposure. This includes victims of obvious traffic accidents. In one minor traffic accident, five teenagers died from CO poisoning while they waited to be rescued.

In 62 of the vehicle-exposure deaths, a motor vehicle was running in a closed space, usually a basement or garage. In twelve of these, work was being performed on the vehicle.

In one case, a 55-year-old woman was found dead at the bottom of her basement stairs after her neighbor had jump-started her car and left it running in the basement so that the lady could get to work. In another case, three elderly persons died when one of them, a 79-year-old

Table 2

Accidental Carbon Monoxide Fatalities (333)

<i>Circumstances of Exposure</i>	
Motor Vehicles	276 (83%)
Parked	173
In Closed Space	62
Other	41
No motor vehicle involved	57 (17%)
Heating Systems Involved	47

man, ran his sister's car in the basement so that he could add fluid. His 76-year-old wife was found dead in the upstairs bedroom and his 69-year-old sister, a few feet from her car. In other cases, stereo systems and CB radios were being installed in running vehicles in basements and garages.

Fatal CO Exposure Not Involving Vehicles

From 1972 to 1985, there were 57 deaths from circumstances not involving vehicles. Forty-seven were associated with defective stoves, heaters or appliances, the most common being improperly vented gas furnaces. These situations can lead to recurrent problems that frequently are not identified as being related to CO. Table 4 illustrates the number of deaths associated with use of the various fuels.

The remaining ten non-vehicle deaths included five from the use of charcoal in a closed space, one of a man who was repairing a lawn mower in a basement, two involving work with a gasoline pump in a well house, and one involving use of a propane heater in an automobile.

Many of these victims were found unconscious or dead in their homes. Importantly, many had recently complained, some to medical professionals, about nonspecific symptoms that now can be attributed to CO exposure. These symptoms were most commonly headache, nausea, vomiting, dizziness, confusion, irritability, and double vision. Examples were also seen of deaths or illness of family members spread over considerable periods of time that were recognized only too late to have CO exposure as their probable cause. These are examples that should be carefully noted by rescue personnel, since only they have the opportunity to see the situations in which these exposures occur.

On a Thursday night, a 40-year-old woman was transported to the emergency room because of dizziness and weakness. She had a history of diabetes and heart disease. In the ER she was given intravenous dextrose, and then she was sent home. Later that same night, her 24-year-old son was brought to the ER in a coma. The hospital personnel called the home in an attempt to obtain

Table 3

Fatal CO Poisonings from Vehicles Other Than Parked With Engine Running With Victims Inside

Deaths	Cause
11	Car exhaust obstructed by: mud, snow, weeds, damaged bumper, mattress
22	Auto accident, vehicle immobilized
8	Car motor running in basement, victims in the house

Table 4

Deaths Associated With Fuels Used For Heating

Fuel	Deaths
Natural Gas	31
Kerosene	4
Fuel Oil	1
Coal	2
Charcoal	5
Unknown	9

some information concerning the son, but were unable to get an answer. On Saturday morning, a relative found the woman dead. Her husband and fifteen-year-old son were in a confused, comatose state with possible paralysis. They were transported to the ER by ambulance. The culprit was a gas furnace leaking dangerous levels of CO.

In another case, a 21-year-old pregnant woman was found dead and her husband unconscious in their mobile home after the husband had failed to appear for a job. The couple had gone to the emergency room the night before because they both had diarrhea and vomiting. Their furnace had reportedly been giving them problems for several weeks.

A 21-year-old woman went to visit her husband, a resident of military base housing. On the first evening of her visit, she presented to the emergency room with unconsciousness. She subsequently died of suspected pneumonia. The family was further grieved to discover the pet dog dead upon their arrival home from the funeral. Approximately three weeks later, the husband was found dead in the apartment. He had asked base personnel to check his furnace two days earlier. His blood carboxyhemoglobin level was 65%, a lethal level. On reexamination, the furnace flu was found to be obstructed by a bird's nest.

Carbon monoxide poisoning is among the most common causes of accidental deaths in North Carolina. Judging from the frequency of death, accidental nonfatal CO exposure must also be an extremely common occurrence. The symptoms of CO exposure are nonspecific, so many such occurrences go unrecognized, even if the victims seek medical attention. In the exposure situation, observant, knowledgeable rescue personnel can provide insight that can be life-saving.

Other Sources of Potentially Dangerous CO Levels

CO is released into the atmosphere by natural as well as human-made sources. Some of the sources are oxidation of atmospheric methane, coal burning, forest fires, volcanoes, agricultural burning and solid waste disposal.

However, the internal combustion engine is our largest source of CO. From 1940 through 1968, there was a dramatic increase in CO emissions in the U.S. due to the increased use of the automobile. Since 1970, automobile CO emission has declined due to the installation of emission control devices.

CO concentration levels are higher in urban areas with dense traffic and tend to peak during the morning and evening rush hour traffic. CO emission depends on vehicle speed, traffic volume and meteorological conditions. Emission decreases with increasing vehicular speed so that even with dense traffic, high-speed highways tend to yield lower CO concentrations than busy city streets.

In special situations such as in underground garages, tunnels, and loading platforms, CO concentrations can reach dangerously high levels for extended periods. It is recommended that CO monitoring devices be installed to sound an alert when levels begin to exceed safe limits, generally 50 parts per million.

Another frequent source of CO exposure is cigarette smoking. Cigarette smoke can reach concentrations of 400 parts per million of CO and produce blood carboxyhemoglobin levels as high as 18%. The average carboxyhemoglobin level for smokers is 3% to 10% and the average level for nonsmokers is 1%.

The chronic, low-level exposures are suspected of contributing to the development of heart disease and to the worsening of symptoms in people who already have heart or lung diseases.

As the case examples of accidental CO poisonings demonstrate, faulty or improperly ventilated heating systems, faulty appliances, and airtight structures can contribute to accidental acute CO poisoning.

Mechanism of CO Poisoning

Carbon Monoxide enters the body through the respiratory system and its toxic and often lethal effects are associated with its binding power with the hemoglobin molecule.

The respiratory and cardiovascular systems work together to provide the essential oxygen for the tissues of

the body. The oxygen binds with the hemoglobin molecule in the red blood cell and is transported to the tissues. However, hemoglobin has an affinity for CO that is 230 to 270 times greater than that for oxygen. A hemoglobin molecule exposed to CO will bind with the CO and displace the oxygen. This means that a red blood cell that is exposed to one part carbon monoxide and about 200 parts oxygen will bind equal amounts of the two gases. Therefore, carbon monoxide in small amounts reduces the oxygen carrying capacity of the blood severely and causes damage to tissues resulting from inadequate oxygen availability. This condition is called "tissue hypoxia," a term meaning low oxygen.

Since CO poisoning causes tissue hypoxia, the signs and symptoms are related to tissues with the greatest oxygen consumption, the brain and heart muscle. Many variables affect the CO level reached by individuals and how rapidly these levels are reached. Some of the variables are:

- 1 Concentration of CO
- 2 Length of exposure
- 3 Respiratory rate and depth
- 4 Level of oxygen in the air
- 5 Age of the individual
- 6 Other underlying disease (lung disorder, heart disease, anemia, etc.)

The effects of hypoxia due to CO vary and may include the following:

Oxygen deficit to the brain may cause central nervous system complications such as uncontrolled movements or alterations in personality and cognitive function. More frequently, it will cause throbbing headache, dizziness, visual deficiency or blindness, central hearing loss, nausea and vomiting and general weakness. The victim may appear intoxicated. These symptoms may be of gradual onset and appear very flu-like.

Oxygen deficit to the heart may cause heart rhythm disturbances and angina. Patients with underlying coronary artery disease may be placed in a precarious situation since tissue hypoxia could cause the heart to increase its rate to provide more oxygen for peripheral tissues while the heart muscle itself is deprived of oxygen.

The skin may appear flushed, cyanotic, pink or pale. The classic "cherry red skin" was an uncommon finding in most of the reports we reviewed, especially in the subacute cases.

The response to the carbon monoxide level in the blood is extremely variable. However, the following COHb levels generally produce these effects:

- 1-10%: May produce no prominent symptoms.
- 10-20%: May produce headache, nausea, and vomiting.
- 20-30%: May produce headache, irritability, fatigue,

poor judgment, dizziness and impaired vision.

40-50%: May produce headache, confusion, collapse, fainting on exertion.

60-70%: Will produce loss of consciousness, intermittent seizures, respiratory failure, death unless treatment is begun rapidly.

80%: Rapidly fatal.

Special Danger to Fire Fighters

The acute exposure of most interest to fire fighters is obviously that associated with fires. Several studies have demonstrated rapid build-up of extremely high levels of CO during the evolution of a fire.

In a series of routine structure fires in Baltimore, fire fighters were directly exposed to CO levels above 5,000 ppm (0.5000%) in 10% of the cases with a maximum exposure to one fire fighter of 27,000 ppm or 2.7%. Many of these individual exposures would have been immediately lethal had the fire fighters lost the use of their breathing equipment. It is clear that the danger of exposure to carbon monoxide alone justifies the use of breathing equipment during the fighting of any structure fire.

The duration of the hazard from carbon monoxide after the fire in a structure has been extinguished depends upon the degree of ventilation. Confined spaces such as cellars or enclosed pantries are especially dangerous. The clearance to work without breathing equipment must obviously be a judgment; but generally the danger must be considered to be present until the entire building has been completely opened and ventilated.

Wildland fires also produce a CO exposure hazard for fire fighters. Atmospheric levels as high as 50,000 ppm have been recorded by remote sensors in the immediate area of a large forest fire. Blood carboxyhemoglobin levels of 10% to 14% were noted in nonsmoking fire fighters involved in clean-up operations at a large fire in Hyde County in 1984. As would be expected, only personnel on the down-wind side of the fire experienced these exposures, while those up-wind from the fire had normal levels. These findings document the need to rotate personnel into and out of the high exposure areas during heavy fire conditions.

Treatment

CO poisoning or suspected CO poisoning should always be regarded as a medical emergency calling for prompt intervention. Treatment should begin immediately with removal of the victim from the source of the gas. The victim should then be given the highest concentration of inspired oxygen that the rescuers have available. Oxygen will increase tissue oxygenation and decrease carboxy-

hemoglobin half-life. The half-life of carboxyhemoglobin while the subject is breathing room air is approximately 240 minutes. This is decreased to 40 minutes with administration of 100% oxygen. If it is possible to draw a blood sample prior to beginning oxygen therapy, this is recommended. However, oxygen therapy should never be withheld while waiting for a confirmed diagnosis of CO intoxication.

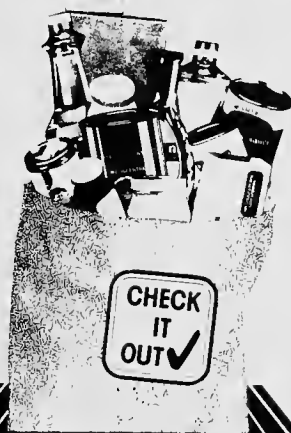
In the hospital, oxygen therapy should continue until the carboxyhemoglobin level has fallen to 1%, and many experts suggest that it may be beneficial to continue with oxygen therapy beyond this point in patients with evi-

dence of cerebral dysfunction. Some patients with extremely high levels, and evidence of severe brain dysfunction, might benefit from administration of pure oxygen in a pressurized chamber (hyperbaric oxygenation). ■

Reference

- 1 The deaths we review are those investigated by the Office of the Chief Medical Examiner of North Carolina during 1972-1985.

Before you buy a product . . .



- ✓ Read the label
- ✓ Check the package

If *anything* seems wrong, tell the store manager.

✓ When you open it, **CHECK IT OUT** again. If it looks or smells wrong, take it back.

— A message from this magazine and the Food and Drug Administration

Which Medical Specialist for You?

The American Board of Medical Specialties

This helpful information on medical specialties and specialists is reprinted from a booklet of the same title published by the American Board of Medical Specialties* (ABMS).

Everyone knows what a "medical doctor" is — a physician who has had years of training to understand the diagnosis, treatment and prevention of disease. The basic training of a physician specialist includes four years of premedical education in a college or university, four years of medical school, and after receiving the M.D. degree, at least three years of specialty training under supervision (called a "residency"). Training in various subspecialties within the general specialties of internal medicine, obstetrics & gynecology, pathology, pediatrics and surgery can take two to three years longer.

The process most widely used by physicians to tell whether and why you are sick is to ask you and/or your family members questions about your health and your past medical history. This process, called "taking a history," is usually followed by an appropriate examination of your body (a "physical examination") to determine how well it is functioning and whether there are signs of disease. Doctors also use a variety of tests such as x-rays, other imaging techniques, and additional procedures to evaluate your health and identify any diseases or other health problems which may be present. Some of these diagnostic procedures (e.g. cardiac catheterization, CAT scans, biopsy of body tissues) are very complicated. They call for many years of training in order to use them safely and accurately.

Then the doctor will recommend what treatment is needed, if any. Treatment may involve surgery (there are many types of surgical specialists), medication, or other complex procedures.

The complexity of the body's structure and the way it functions call for high levels of skill in understanding body systems and in knowing the effect that each system has

on the whole, in health and in disease. That is why, today, most physicians choose to specialize.

Specialists are doctors who concentrate on certain body systems, specific age groups, or on complex scientific techniques developed to diagnose or treat certain types of disorders. Specialties in medicine developed because of the rapidly expanding body of knowledge about health and illness and the constantly evolving new treatment techniques for disease. Today, no one doctor can hope to master the total field of medical knowledge or maintain skills in all diagnostic tests, treatments, and procedures.

A subspecialist is a physician who has completed training in a general medical specialty and then takes additional training in a more specific sub-area of that specialty called a subspecialty. This training increases the depth of knowledge of the specialist in that particular field. For example, cardiology is a subspecialty of internal medicine; pediatric surgery is a subspecialty of surgery; and child psychiatry is a subspecialty of psychiatry. The training of a subspecialist within a specialty requires an additional one or more years of full-time education in a program called a "fellowship."

Training of a Specialist

The training of a specialist begins after the doctor has received the M.D. degree from a medical school, in what is called a residency. Resident physicians dedicate themselves for three to seven years to full-time experience in a hospital or ambulatory care setting, caring for patients under the supervision of experienced teaching specialists. Educational conferences and research experience are also part of that training. A doctor in training to be a specialist is called a "resident," although the first year of residency used to be called an "internship."

In each state, the privilege to practice medicine is governed by state law and is not designed to recognize the knowledge and skills of a trained specialist. The physician is licensed to practice general medicine and surgery

*The American Board of Medical Specialties, One American Plaza, Suite 805, Evanston, IL 60201. Reprinted with permission. The booklet is available from the Board at the above address for 25 cents a copy.

by a State Board of Medical Examiners after passing a licensure examination. Each state has its own examining procedure to license physicians, and this board sets the general standards for all physicians.

Who Credentials a Specialist and/or Subspecialist?

Specialty boards certify physicians as having met certain published standards. There are 23 specialty boards that are recognized by the American Board of Medical Specialties (ABMS) and the American Medical Association (AMA). All of the specialties and subspecialties recognized by the ABMS and the AMA are listed in the brief descriptions that follow. Remember, a subspecialist first must be trained and certified as a specialist.

In order to be certified as a medical specialist by one of these recognized boards, a physician must complete certain requirements. Generally, these include:

- 1 Completion of a course of study leading to the M.D. or D.O. degree in a recognized school of medicine.
- 2 Completion of three to seven years of full-time training in an accredited residency program designed to train specialists in that field.
- 3 Some specialty boards require assessments of individual performance and competence from the residency training director or from the chief of service in the hospital where the specialist has practiced.
- 4 Most specialty boards require that the person who seeks certification have an unrestricted license to practice medicine in order to take the certification examination.
- 5 Some boards require that the doctor have a period of experience in full-time practice in the specialty prior to examination for certification — usually two years following training.
- 6 Finally, each candidate for certification must pass a written examination given by the specialty board. Sixteen of the 23 specialty boards also require an oral examination conducted by senior specialists in that field. Candidates who have passed the exams and other requirements are then given the status of "Diplomate" and are certified as specialists. A similar process is followed for specialists who want to become subspecialists.

Some boards issue certificates for a limited period of time, usually seven to ten years. In order to retain certification, diplomates of those boards must become "re-certified," and must periodically go through an additional process involving continuing education in the specialty, review of credentials and further examination. Some boards that may not require recertification have provided voluntary recertification with similar requirements.

How To Determine If a Physician Is a Certified Specialist or Subspecialist

Certified specialists are listed in directories published by the American Board of Medical Specialties (ABMS). These include individual directories for each specialty and also the ABMS Compendium of Certified Medical Specialists. The ABMS Compendium can be found in most public libraries, hospital libraries and medical libraries. Directories are also available in university libraries. Alternatively, you could ask for that information from your county or state medical society (North Carolina Medical Society, 222 N. Person St., Raleigh 27611; 919/833-3836), or from the American Board of Medical Specialties, or from a particular specialty board (the list of specialty boards appears in the ABMS booklet from which this excerpt is taken).

Description of Recognized Specialties and Subspecialties

Allergy and Immunology

An allergist-immunologist is a certified internist or pediatrician expert in the evaluation, physical and laboratory diagnosis, and management of disorders potentially involving the immune system. Selected examples of such conditions include asthma, anaphylaxis, rhinitis, eczema, urticaria, and adverse reactions to drugs, foods, and insect bites as well as immune deficiency diseases (both acquired and congenital), defects in host defense, and problems related to autoimmune disease, organ transplantation or malignancies of the immune system. The scope of this specialty is ever-widening as our understanding of the immune system develops. Selected experts may be additionally certified in "Diagnostic Laboratory Immunology" after additional training in the various laboratory procedures required to analyze both the function and malfunction of the immune system.

Anesthesiology

The anesthesiologist is a physician-specialist who, following medical school graduation and at least four years of postgraduate training, has the principal task of providing pain relief and maintenance, or restoration, of a stable condition during an operation, an obstetric or diagnostic procedure. The anesthesiologist assesses the risk of the patient undergoing surgery and optimizes the patient's condition prior to, during and after surgery. Anesthesiologists diagnose and treat acute and long-standing pain problems. Anesthesiologists diagnose and treat patients who have critical illnesses or are severely injured. Anes-

thesiologists direct resuscitation in the care of patients with cardiac or respiratory emergencies including the provision of artificial ventilation. They also supervise and teach others involved in anesthesia, respiratory and intensive care. Anesthesiologists may specialize in Critical Care Medicine as practiced in critical care and intensive care units, post-anesthesia recovery rooms, and other settings.

Critical Care Medicine: The anesthesiologist who specializes in Critical Care Medicine is a physician who after completion of anesthesiology training must receive additional training in critical care because the requisite knowledge and skills extend beyond anesthesiology training and cross traditional specialty lines. The primary work place is an intensive or critical care unit. Anesthesiologists trained in critical care are qualified to diagnose, treat and support patients with multiple organ system dysfunction. In addition, they may have administrative responsibilities for intensive care units and may participate in the training and medical direction of essential health care professionals such as nurses and respiratory therapists. The critical care anesthesiologist, in addition to providing direct patient care, may also facilitate and coordinate patient care among the primary physician, the critical care staff, and other specialists.

Colon and Rectal Surgery

A colon and rectal surgeon is a fully trained general surgeon who has had additional training in the diagnosis and treatment of diseases of the intestinal tract, rectum and anus. These include such anal conditions as hemorrhoids, fissures, and fistulas, and such colon and rectal diseases as polyps, cancer, colitis and diverticulitis.

Dermatology

A dermatologist is a physician concerned with the prevention, diagnosis, and treatment of benign and malignant disorders of the skin and related tissues of the mouth, external genitalia, hair and nails. The dermatologist also diagnoses and treats a number of diseases transmitted through sexual activity. Dermatologists use many diagnostic procedures including microscopic and microbiologic examination of the skin and its secretions. Treatment methods used by the dermatologist include externally applied, injected and internal medications, selected x-ray and ultraviolet light therapy, and a range of surgical procedures using instruments including the scalpel, surgical curette, electrosurgical unit, freezing surgical unit, and laser.

With this background and knowledge, the dermatologist is singularly qualified to advise on the care of normal

skin, to prescribe measures to maintain the skin in a state of health, to make accurate diagnoses and administer treatment for all skin diseases and the skin manifestations of internal diseases and sexually-transmitted diseases. In addition, the dermatologist has had training and experience in the management of skin cancers, moles, and other tumors of the skin and in the use of the various techniques for the correction of cosmetic defects of the skin. Patients seeking a dermatologist ordinarily may come directly or be referred by another physician.

Emergency Medicine

Emergency Medicine is the medical specialty that focuses on the immediate decision making and action necessary to prevent death or any further disability. It is primarily hospital emergency department based, but with extensive prehospital responsibilities for emergency medical systems.

The emergency physician provides immediate initial recognition, evaluation, care and disposition of a generally undifferentiated population of patients in response to acute illness and injury. The care provided by the emergency physician is episodic in nature and involves a full spectrum of physical and behavioral conditions.

Family Practice

Family Practice is the primary medical specialty which is concerned with the total health care of the individual and the family. It is the specialty in breadth which integrates the traditional biological and clinical sciences with the behavioral and preventive aspects of the practice of medicine and is not limited by any particular age, sex, organ system or disease entity.

Training in Family Practice encompasses knowledge and skills which prepare the physician for a unique role as a personal physician who provides comprehensive health care to the individual and family.

Internal Medicine

A general internist is a physician who provides scientifically based, empathic care for the nonsurgical illnesses of adolescents and adults. This care tends to be characterized by a mutual personal commitment between doctor and patient, by stability over time, by substantial breadth, and by an appropriate attention to elements of human support, sensitivity, and concern. It is marked by technical sophistication and major professional expertise. The general internist provides continuing, comprehensive care for common and complex multisystem illnesses in the ambulatory care as well as the hospital setting.

The general internist also functions as a consultant to other specialists and is competent to handle critically ill patients and nonsurgical disorders in adolescents and adults seeking aid in the emergency room setting. Well-trained internists are unique in their ability to deliver with broad competence primary, secondary, and tertiary care.

Internists may subspecialize in:

Cardiovascular Medicine: Cardiologists subspecialize in diseases of the heart, lungs, and blood vessels and manage complex cardiac conditions such as heart attacks and life-threatening abnormal heart beat rhythms, in settings such as the coronary care unit of a hospital. They often perform complicated diagnostic procedures such as cardiac catheterizations.

Critical Care Medicine: The internist-intensivist subspecializes in managing life-threatening acute disorders in intensive care units and other settings. Shock, coma, heart failure, respiratory arrest, drug overdoses, massive bleeding, diabetic acidosis, and kidney shutdown are examples of conditions requiring critical care by internists.

Diagnostic Laboratory Immunology: This is a subspecialty field in which laboratory tests and complex procedures are used to diagnose and treat disorders characterized by defective responses of the body's immune systems.

Endocrinology: The endocrinologist concentrates on disorders of the internal (endocrine) glands such as the thyroid and adrenal glands. Endocrinology also deals with disorders such as diabetes, metabolic and nutritional disorders, pituitary diseases, and menstrual and sexual problems.

Gastroenterology: The subspecialty of the digestive organs involves the stomach, bowels, liver, gallbladder, and related organs. The gastroenterologist treats conditions such as abdominal pain, ulcers, diarrhea, cancer, and jaundice, and consults with surgeons when abdominal operations are indicated. Gastroenterologists visualize the hollow organs through lighted endoscopes, and through these flexible tubes can biopsy lining tissues and remove small polyps.

Hematology: Hematologists subspecialize in diseases of the blood, spleen, and lymph glands. They treat conditions such as anemia, clotting disorders, sickle cell disease, hemophilia, leukemia, and lymphoma, and may perform special types of transfusions and biopsy the bone marrow for analysis.

Infectious Disease: These subspecialists deal with infectious diseases of all types and in all organs. Conditions requiring selective use of antibiotics call for this special skill. Patients with fevers which have not been

explained are often diagnosed and treated by these subspecialists.

Medical Oncology: The medical oncologist specializes in the diagnosis and treatment of all types of cancer and other benign and malignant tumors. These subspecialists also decide on and administer chemotherapy for malignancy as well as consult with surgeons and radiotherapists on treatment for cancer.

Nephrology: The nephrologist is concerned with disorders of the kidney, hypertension, fluid and mineral balance, dialysis of body wastes when the kidneys do not function, and consultation with surgeons about kidney transplantation.

Pulmonary Diseases: Pulmonary Disease is the subspecialty concerned with diseases of the lungs and other chest tissues. The pulmonologist diagnoses and treats pneumonia, cancer, occupational diseases, bronchitis, emphysema, and other complex disorders of the lungs. Pulmonologists test lung functions in many ways, endoscope the bronchia airways, and prescribe and monitor mechanical assistance to ventilation. Many pulmonary disease experts supervise critical care units.

Rheumatology: The rheumatologist is concerned with diseases of joints, muscle, bones, and tendons. The rheumatologist diagnoses and treats arthritis, various types of back pain, muscle strains, common athletic injuries, and rare diseases of the connective tissue and arteries in many body systems called "collagen" diseases. He may work closely with other specialists such as physiatrists and orthopaedic surgeons.

Allergy & Immunology: The subspecialty of allergy and immunology is represented by a conjoint board of the American Board of Internal Medicine and the American Board of Pediatrics, called the American Board of Allergy and Immunology.

Neurological Surgery

Neurological Surgery is a discipline of medicine which deals with the diagnosis, evaluation and treatment of diseases of the brain, spinal cord, and nerves, including the blood supply to these structures. The Neurological Surgeon is a specialist involved in the operative and non-operative management, diagnosis, evaluation, treatment, critical care and rehabilitation of patients with disorders of the nervous system.

Neurology

A neurologist is a physician concerned with the diagnosis and treatment of all categories of disease involving the

central, peripheral and autonomic nervous systems, including their coverings, blood vessels, and all effector tissues, such as muscle. For these diseases he/she is often the principal physician and may render all levels of care commensurate with his/her training. He/she should have completed training in an accredited training program and may be certified through examination by the American Board of Psychiatry and Neurology, in Neurology or in Neurology with Special Qualifications in Child Neurology.

Nuclear Medicine

Nuclear medicine is the clinical and laboratory medical specialty that employs for diagnosis, therapy and research the nuclear properties of radioactive and stable nuclides to evaluate metabolic, physiologic, and pathologic conditions of the body. A specialist in nuclear medicine is a physician who has been awarded a medical degree from an approved medical or osteopathic school, has satisfactorily completed two or more years of preparatory residency training and two years of nuclear medicine training in accredited residency programs, and who has satisfactorily passed rigorous written examination encompassing the medical uses of radioactive materials and the related physical and biological sciences.

The professional competence of nuclear medicine physicians includes: Special knowledge in the physical sciences encompassing the fundamentals of nuclear physics and nuclear magnetic resonance; the principles and operations of radiation detection and nuclear imaging instrumentation systems; statistics and fundamentals of computer sciences; the biologic effects of radiation exposure and the principles of radiation safety and protection; the production, biochemistry, and pharmacology of radioactive pharmaceuticals; and the diagnostic and therapeutic uses of radionuclides.

The nuclear medicine specialist serves as a consultant to physicians and must be prepared to obtain by means of history and physical examination pertinent information from patients, and to select and carry out appropriate nuclear medicine diagnostic procedures and nuclear medicine therapy if indicated.

The nuclear medicine physician must have broad knowledge and experience in medicine and must be capable of extending the scope of nuclear medicine as the specialty evolves and expands.

Obstetrics and Gynecology

A specialist in Obstetrics and Gynecology is a physician who is certified by The American Board of Obstetrics and Gynecology, Inc. These individuals have been prepared to provide medical and surgical care for disorders

that affect the female reproductive system, the fetus or the newborn. These physicians have particular knowledge and skills which enable them to serve as consultants to physicians who practice in other areas of medicine.

A specialist in Obstetrics and Gynecology may subspecialize in:

Gynecologic Oncology: A gynecologic oncologist is a specialist in Obstetrics and Gynecology who is trained and capable in the comprehensive management of patients with gynecologic cancer and whose present activity includes the practice of gynecologic oncology in an institutional setting wherein all the effective forms of cancer therapy are available. Comprehensive management should include those diagnostic and therapeutic procedures necessary for the total care of patients with gynecologic cancer or complications resulting therefrom.

Maternal-Fetal Medicine: A specialist in Maternal-Fetal Medicine is a specialist in Obstetrics and Gynecology who by virtue of additional education is prepared to care for or consult on patients with high risk pregnancies. This requires advanced knowledge in the medical and surgical complications of pregnancy and their effect on both the mother and the fetus. It also requires expertise in the most current diagnostic and treatment modalities used in the care of patients with high risk pregnancies. Advanced knowledge of newborn adaptation is also necessary so that there may be a continuum of excellence in care from the fetal to newborn periods.

Reproductive Endocrinology: A Reproductive Endocrinologist is a specialist in Obstetrics and Gynecology who has been appropriately trained and is capable of managing complex problems relating to Reproductive Endocrinology and Infertility, one whose current professional activity involves the practice of Reproductive Endocrinology in an institutional setting wherein essential diagnostic and therapeutic facilities are being appropriately utilized.

Ophthalmology

Ophthalmologists are concerned with comprehensive care of the eyes and vision. They are the only practitioners medically trained to diagnose and treat all eye and visual problems including vision services (glasses and contact lenses), and medical disorders of the eye including surgical procedures for treatment.

Orthopaedic Surgery

Orthopaedic Surgery is the medical specialty that includes the preservation, investigation and restoration of the form and function of the extremities, spine and associated

structures by medical, surgical and physical means. Orthopaedic surgeons are involved with the care of patients whose musculoskeletal problems are present at birth or develop at any time during their lifetime. Congenital deformities, trauma, infections, tumors and metabolic disturbances of the musculoskeletal system are problems cared for by the orthopaedic surgeon. They are also concerned with all problems, as well as primary and secondary muscular problems. They are also involved in the care of patients who manifest the effects of central or peripheral nervous system lesions on the musculoskeletal system.

Otolaryngology

An otolaryngologist-head and neck surgeon is a physician who has been prepared by accredited residency programs to provide comprehensive medical and surgical care of patients with diseases and disorders that affect the ears, the respiratory and upper alimentary systems and related structures: the head and neck in general. The required five years of postgraduate specialty training must include one or more years of general surgery and three or more years of otolaryngology-head and neck surgery in approved residency programs.

The otolaryngologist-head and neck surgeon has a command of the core of knowledge, skills and understanding of:

The basic medical sciences relevant to the head and neck; the respiratory and upper alimentary systems; the communication sciences, including knowledge of audiology and speech-language pathology; the chemical senses and allergy, endocrinology and neurology as they relate to the head and neck; the clinical aspects of diagnosis and the medical and/or surgical therapy or prevention for diseases, neoplasms, deformities, disorders and/or injuries of the ears, the respiratory and upper alimentary systems, the face, jaws and the other head and neck systems. Head and neck oncology and facial plastic and reconstructive surgery are fundamental areas of expertise.

Pathology

Pathology is that specialty of the practice of medicine dealing with the causes and nature of disease. It contributes to diagnosis, prognosis, and treatment through knowledge gained by the laboratory application of the biologic, chemical, and physical sciences to man, or materials obtained from man.

A certified specialist in pathology is a physician who voluntarily undertook and successfully completed an approved graduate medical education program in pathology

and an evaluation process, including an examination administered by The American Board of Pathology. The purpose of the certification process is to assure the public and the medical profession that the pathologist has a level of knowledge, skill and other abilities deemed necessary for the scientific practice of pathology.

Pathologists are prepared to use their skills and knowledge for the diagnosis, exclusion, and monitoring of disease by means of information gathered from the microscopic examination of tissue specimens, cells, and body fluids, and from clinical laboratory tests on body fluids and secretions. The application of the resulting information to patient care requires pathologists to be especially knowledgeable in the management of laboratories and in data processing and to be conversant with new developments in "high" technology. Pathologists have the clinical training as well as the laboratory expertise to function as consultants to physicians practicing clinical medicine and to patients.

A certified specialist in pathology may subspecialize and become certified in one of the following areas:

Blood Banking: A physician specializing in blood banking is responsible for the maintenance of an adequate blood supply, blood donor and patient-recipient safety, and appropriate blood utilization. Pretransfusion compatibility testing and highly specialized testing procedures for antibodies under his/her direction assure the clinician and the patient that blood transfusions, when indicated, are as safe as possible. The blood bank specialist directs the preparation and safe use of specially prepared blood components, including red blood cells, white blood cells, platelets, and plasma constituents.

Chemical Pathology: A chemical pathologist is expert in the biochemistry of the human body as it applies to the understanding of the cause and progress of disease. Chemical pathology entails the application of biochemical data to the exclusion, detection, confirmation, or monitoring of a given disease process. The chemical pathologist functions as a clinical consultant in the diagnosis and treatment of human disease.

Dermatopathology: A dermatopathologist is expert in diagnosing and monitoring diseases of the skin including infections, immunologic, degenerative, and neoplastic diseases. This entails the examination and interpretation of specially prepared tissue sections, cellular scrapings and smears of skin lesions by means of light microscopy, electron microscopy, and fluorescence microscopy. In order to fulfill his consulting role to the patient and to the patient's physician, the dermatopathologist is required to have a good general knowledge of medicine and an in-depth knowledge of dermatology, microbiology, parasitology, new technology, and laboratory management.

Forensic Pathology: A forensic pathologist is expert in investigating and evaluating cases of sudden, unexpected, suspicious, and violent death as well as other specific classes of death defined by law. The forensic pathologist serves the public as coroner or medical examiner or by performing medicolegal autopsies for such officials.

Hematology: A hematologist-pathologist is expert in diseases that affect blood cells, blood clotting mechanisms, bone marrow, and lymph nodes. This specialist has the knowledge and technical skills essential for the laboratory diagnosis of anemias, leukemias, lymphomas, bleeding disorders, and blood clotting disorders. The hematologist/pathologist functions as a consultant to all physicians and works closely with clinical hematologists and oncologists (cancer specialists).

Immunopathology: An immunopathologist is concerned with the scientific study of the causes, diagnosis, and prognosis of disease by the application of immunological principles to the analysis of tissues, cells, and body fluids. The immunopathologist is required to have a detailed understanding of the immunologic basis of disease from the perspective of anatomic and clinical pathology and to have the knowledge and ability to interpret laboratory data in relation to patients with immunologic diseases and organ transplant recipients.

Medical Microbiology: A medical microbiologist devotes expertise to the isolation and identification of microbial agents that cause infectious disease. Viruses, bacteria, molds and fungi, as well as single-cell and larger parasites are identified and, where possible, tested for susceptibility to appropriate antimicrobial agents. This pathologist frequently acts as consultant to primary care physicians in the diagnosis and selection of therapy for patients with infectious disease.

Neuropathology: A neuropathologist is expert in the diagnosis of disease of the nervous system and skeletal muscles and functions as a consultant primarily to neurologists and neurosurgeons. The neuropathologist is knowledgeable in the infirmities of man as they affect the nervous and neuromuscular systems be they degenerative, infective, metabolic, immunologic, neoplastic, vascular, or physical in nature. In the diagnosis of these diseases, the neuropathologist employs the special skills and techniques necessary for the scientific study of tissues, cells, and body fluids.

Pediatrics

Pediatrics is the specialty of medical science concerned with the physical, emotional, and social health of children from birth to young adulthood. Pediatric care encompasses a broad spectrum of health services ranging from

preventive health care to the diagnosis and treatment of acute and chronic diseases.

Pediatrics is a discipline that deals with biological, social, and environmental influences on the developing child and with the impact of disease and dysfunction on development. Children differ from adults anatomically, physiologically, immunologically, psychologically, developmentally, and metabolically. The pediatrician understands this constantly changing functional status of his/her patients incident to growth and development, and the consequent changing standards of "normal" for age.

A pediatrician is a medical specialist who is primarily concerned with the health, welfare and development of children and is uniquely qualified for these endeavors by virtue of interest and initial training. Maintenance of these competencies is achieved by experience, training and continuous education.

A pediatrician is able to define accurately the child's health status, as well as being able to serve as a consultant and to make use of other specialists as consultants. Because children's welfare is heavily dependent on the home and family, the pediatrician supports efforts to create a nurturing environment. Such support includes education about healthful living and anticipatory guidance for both patients and parents.

A pediatrician participates at the community level in preventing or solving problems in child health care and publicly advocates the causes of children.

In addition to the general comprehensive pediatrician, there are subspecialists in pediatrics in a number of sub-disciplines such as cardiology, neonatology, endocrinology, hematology-oncology, nephrology, and pulmonology. A later edition of this pamphlet (to be published by the ABMS) will include a listing and definitions of these pediatric subspecialties.

The subspecialty of allergy and immunology is represented by a conjoint board of the American Board of Pediatrics and the American Board of Internal Medicine, called the American Board of Allergy and Immunology.

Physical Medicine and Rehabilitation

Physical Medicine and Rehabilitation (also referred to as Rehabilitation Medicine, or Physiatry) is the medical specialty concerned with evaluation and functional restoration of patients with disabilities regardless of etiology. Some of the more common conditions which produce the disabilities are stroke, multiple sclerosis, Parkinson's disease, amputation, spinal cord injury, cerebral palsy, arthritis, and trauma.

Plastic Surgery

The specialty of Plastic Surgery deals with the repair, replacement and reconstruction of defects of form and

function of the integument and its underlying musculoskeletal system, with emphasis on the craniofacial structures, the oropharynx, the upper and lower limbs, the breast, and the external genitalia. It includes aesthetic surgery of structures with undesirable form.

Special knowledge and skill in the design and transfer of flaps, in the transplantation of tissues, and in the replantation of structures are vital to these ends, as is skill in excisional surgery, in management of complex wounds, and in the use of alloplastic materials.

Knowledge of surgical design, surgical diagnosis, surgical and artistic anatomy, surgical pathology, surgical oncology, surgical physiology and pharmacology and bacteriology, biomechanics, embryology, and surgical instrumentation are fundamental to this specialty.

The judgment and technical capability for achieving satisfactory surgical results are mandatory qualities for the plastic surgeon.

Preventive Medicine

Preventive Medicine is that specialty which focuses on the health of individuals and defined populations in order to protect, promote and maintain health and well-being, and to prevent disease, disability and premature death.

In addition to the knowledge of basic and clinical sciences and the skills common to all physicians, the distinctive components of Preventive Medicine include:

- 1 Biostatistics
- 2 Epidemiology
- 3 Health services administration
- 4 Environmental and occupational influences on health
- 5 Social and behavioral influences on health
- 6 Measures which prevent the occurrence, progression and disabling effects of disease or injury

Psychiatry

These specialists deal with diagnosis, treatment and prevention of mental, emotional and/or behavioral disorders. They also enhance the adaptation of individuals who are coping with stress, crises, and other problems in living.

A psychiatrist may subspecialize in:

Child Psychiatry: A child psychiatrist is a psychiatrist with specialty qualification in the diagnosis and treatment of children, adolescents and their families.

Radiology

Therapeutic Radiology (Radiation Oncology) is that

branch of Radiology which deals with the therapeutic applications of radiant energy and its modifiers and the study and management of disease, especially malignant tumors.

Diagnostic Radiology is that branch of Radiology which deals with the utilization of all modalities of radiant energy in medical diagnosis and therapeutic procedures utilizing radiations emitted by x-ray tubes, radionuclides, thermographic devices, ultrasonographic devices, and the radio-frequency electromagnetic radiation emitted by atoms.

Nuclear Radiology is that branch of Radiology which involves the analysis and imaging of radionuclides and radiolabeled substances in vitro and in vivo for diagnosis and the administration of radionuclides and radiolabeled substances for the treatment of disease.

Radiological Physics is that branch of medical physics which includes therapeutic radiological physics, diagnostic radiological physics, and medical nuclear physics; including radiation safety.

Therapeutic Radiological Physics is that branch of medical physics which deals with (1) the therapeutic applications of roentgen rays, of gamma rays, of electron and other charged particle beams, of neutrons, and of radiations from sealed radionuclide sources, and (2) the equipment associated with their production and use.

Diagnostic Radiological Physics is that branch of medical physics which deals with (1) the diagnostic applications of roentgen rays, of gamma rays from sealed sources, of ultrasonic radiation, and of radio-frequency radiation, and (2) the equipment associated with their production and use.

Medical Nuclear Physics is that branch of medical physics which deals with (1) the therapeutic and diagnostic application of radionuclides (except those used in sealed sources for therapeutic purposes), and (2) the equipment associated with their production and use.

General Surgery

A general surgeon is a specialist prepared to manage a broad spectrum of surgical conditions affecting almost any area of the body. The surgeon establishes the diagnosis and provides the preoperative, operative and postoperative care to patients and is often responsible for the comprehensive management of the trauma victim. During at least a five-year educational period after obtaining a medical degree, the surgeon has acquired knowledge and technical skill in problems relating to the head and neck, breast, abdominal wall, extremities, and the gastrointestinal, vascular and endocrine systems. The surgeon uses a variety of diagnostic techniques, including endoscopy, for observing internal structures, and may use specialized

instruments during operative procedures. A general surgeon is expected to be familiar with the salient features of other surgical specialties in order to recognize problems in those areas and to know when to refer a patient to another specialist.

Other areas of special expertise are recognized within the discipline of general surgery, requiring additional training and further examination:

General Vascular Surgery: A surgeon with special qualifications in the management of surgical disorders of the blood vessels excluding those to the heart, lungs or brain.

Pediatric Surgery: A surgeon with special qualifications in the management of surgical conditions in premature and newborn infants, children, and adolescents.

Surgical Critical Care: A surgeon with special qualifications in the management of the critically ill patient, particularly the trauma victim, and the postoperative patient in the emergency department, intensive care unit, trauma unit, burn unit, and other similar settings.

Thoracic Surgery

Thoracic surgery encompasses the preoperative evaluation, operative management, and postoperative care of patients with pathologic conditions within the chest. Specifically, it includes the surgery for congenital anomalies,

diseases and injuries of the heart and great vessels, the lungs, esophagus, mediastinum, chest wall and diaphragm in all age groups.

To possess special qualification in thoracic surgery, as recognized in certification by the American Board of Thoracic Surgery, requires the knowledge, experience, and technical skill to diagnose accurately, to operate upon safely and to manage effectively patients with intrathoracic abnormalities that are appropriate to treat surgically. This requires a substantial knowledge of cardiorespiratory physiology, as well as capability in the use of extracorporeal circulation, intra-aortic balloon support, pacemakers, pleural drainage, respiratory support systems, and metabolic and hemodynamic monitoring. Recognizing and differentiating thoracic abnormalities requires skill in endoscopy and other invasive and non-invasive diagnostic techniques.

Urology

A specialist in Urology is a physician who has fulfilled the requirements of, and is certified by, The American Board of Urology. He is competent to manage benign and malignant medical and surgical disorders of the adrenal gland and of the genitourinary system. Urologists have comprehensive knowledge of, and skills in, endoscopic, percutaneous, and open surgery of congenital and acquired conditions of the reproductive and urinary systems and their contiguous structures. ■




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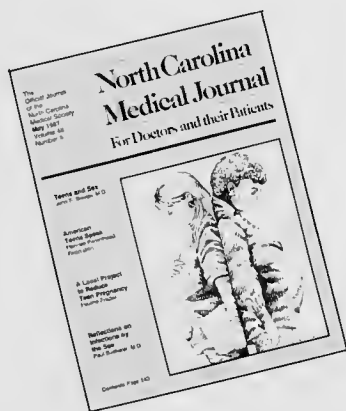
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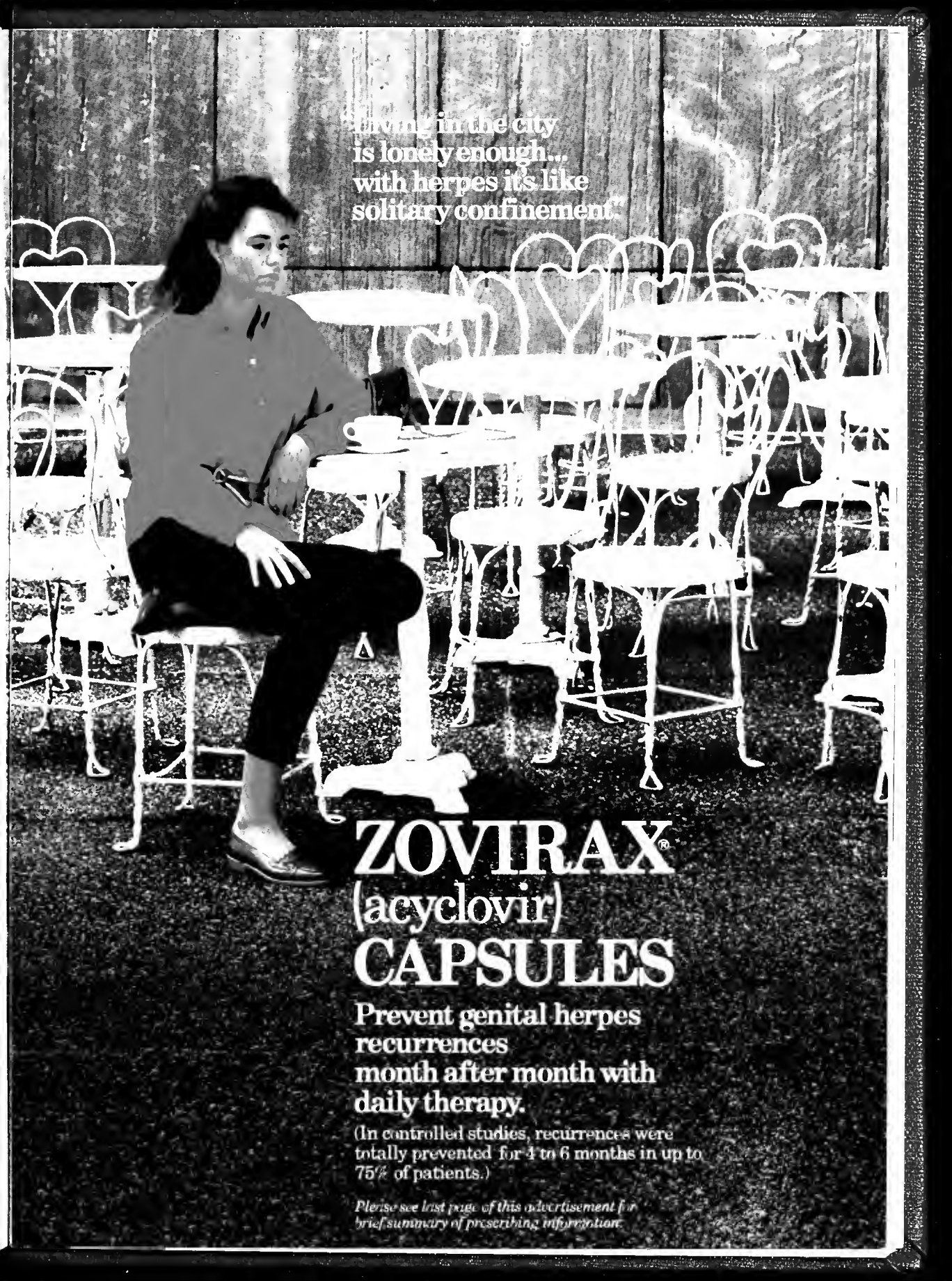
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**Prevent genital herpes
recurrences
month after month with
daily therapy.**

(In controlled studies, recurrences were
totally prevented for 4 to 6 months in up to
75% of patients.)

*Please see last page of this advertisement for
brief summary of prescribing information.*

ZOVIRAX[®] (acyclovir) CAPSULES

Help free your
patients from
recurrences.

Daily therapy

Coping with genital herpes is rarely easy. For some, the worst part is the pain and discomfort of frequent attacks — month after month, year after year. For others, the emotional burden presents a more difficult problem, leading to social isolation, anxiety, and diminished self-esteem.

Prevent or reduce recurrences

Although your patients have to live with herpes, they shouldn't have to suffer. Daily therapy with ZOVIRAX CAPSULES can help free them from the cycle of recurrent genital herpes. For many, one capsule three times a day can suppress recurrences completely while on therapy.

Generally well tolerated

Daily therapy with ZOVIRAX CAPSULES is generally well tolerated. The most frequent adverse reactions reported during clinical trials were headache, diarrhea, nausea/vomiting, vertigo, and arthralgia.

The physical and emotional difficulties posed by genital herpes are unique for each patient. The frequency and severity of recurrent episodes, as well as the emotional impact of the disease, should be considered when selecting daily therapy with ZOVIRAX CAPSULES.

*Please see brief summary of
prescribing information on next page.*



Prevent recurrences month after month* **ZOVIRAX®** (acyclovir) **CAPSULES**

Brief Summary

INDICATIONS AND USAGE: Zovirax Capsules are indicated for the treatment of initial episodes and the management of recurrent episodes of genital herpes in certain patients.

The severity of disease is variable depending upon the immune status of the patient, the frequency and duration of episodes, and the degree of cutaneous or systemic involvement. These factors should determine patient management, which may include symptomatic support and counseling only, or the institution of specific therapy. The physical, emotional and psychosocial difficulties posed by herpes infections as well as the degree of debilitation, particularly in immunocompromised patients, are unique for each patient, and the physician should determine therapeutic alternatives based on his or her understanding of the individual patient's needs. Thus Zovirax Capsules are not appropriate in treating all genital herpes infections. The following guidelines may be useful in weighing the benefit/risk considerations in specific disease categories:

First Episodes (primary and nonprimary infections — commonly known as initial genital herpes):

Double-blind, placebo-controlled studies have demonstrated that orally administered Zovirax significantly reduced the duration of acute infection (detection of virus in lesions by tissue culture) and lesion healing. The duration of pain and new lesion formation was decreased in some patient groups. The promptness of initiation of therapy and/or the patient's prior exposure to Herpes simplex virus may influence the degree of benefit from therapy. Patients with mild disease may derive less benefit than those with more severe episodes. In patients with extremely severe episodes, in which prostration, central nervous system involvement, urinary retention or inability to take oral medication require hospitalization and more aggressive management, therapy may be best initiated with intravenous Zovirax.

Recurrent Episodes:

Double-blind, placebo-controlled studies in patients with frequent recurrences (6 or more episodes per year) have shown that Zovirax Capsules given for 4 to 6 months prevented or reduced the frequency and/or severity of recurrences in greater than 95% of patients. Clinical recurrences were prevented in 40 to 75% of patients. Some patients experienced increased severity of the first episode following cessation of therapy; the severity of subsequent episodes and the effect on the natural history of the disease are still under study.

The safety and efficacy of orally administered acyclovir in the suppression of frequent episodes of genital herpes have been established only for up to 6 months. Chronic suppressive therapy is most appropriate when, in the judgement of the physician, the benefits of such a regimen outweigh known or potential adverse effects. In general, Zovirax Capsules should not be used for the suppression of recurrent disease in mildly affected patients. Unanswered questions concerning the human relevance of *in vitro* mutagenicity studies and reproductive toxicity studies in animals given very high doses of acyclovir for short periods (see Carcinogenesis, Mutagenesis, Impairment of Fertility) should be borne in mind when designing long-term management for individual patients. Discussion of these issues with patients will provide them the opportunity to weigh the potential for toxicity against the severity of their disease. Thus, this regimen should be considered only for appropriate patients and only for six months until the results of ongoing studies allow a more precise evaluation of the benefit/risk assessment of prolonged therapy.

Limited studies have shown that there are certain patients for whom intermittent short-term treatment of recurrent episodes is effective. This

approach may be more appropriate than a suppressive regimen in patients with infrequent recurrences.

Immunocompromised patients with recurrent herpes infections can be treated with either intermittent or chronic suppressive therapy. Clinically significant resistance, although rare, is more likely to be seen with prolonged or repeated therapy in severely immunocompromised patients with active lesions.

CONTRAINDICATIONS: Zovirax Capsules are contraindicated for patients who develop hypersensitivity or intolerance to the components of the formulation.

WARNINGS: Zovirax Capsules are intended for oral ingestion only.

PRECAUTIONS: General: Zovirax has caused decreased spermatogenesis at high doses in some animals and mutagenesis in some acute studies at high concentrations of drug (see PRECAUTIONS — Carcinogenesis, Mutagenesis, Impairment of Fertility). The recommended dosage and length of treatment should not be exceeded (see DOSAGE AND ADMINISTRATION).

Exposure of Herpes simplex isolates to acyclovir *in vitro* can lead to the emergence of less sensitive viruses. The possibility of the appearance of less sensitive viruses in man must be borne in mind when treating patients. The relationship between the *in vitro* sensitivity of Herpes simplex virus to acyclovir and clinical response to therapy has yet to be established.

Because of the possibility that less sensitive virus may be selected in patients who are receiving acyclovir, all patients should be advised to take particular care to avoid potential transmission of virus if active lesions are present while they are on therapy. In severely immunocompromised patients, the physician should be aware that prolonged or repeated courses of acyclovir may result in selection of resistant viruses which may not fully respond to continued acyclovir therapy.

Drug Interactions: Co-administration of probenecid with intravenous acyclovir has been shown to increase the mean half-life and the area under the concentration-time curve. Urinary excretion and renal clearance were correspondingly reduced.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Acyclovir was tested in lifetime bioassays in rats and mice at single daily doses of 50, 150 and 450 mg/kg given by gavage. There was no statistically significant difference in the incidence of tumors between treated and control animals, nor did acyclovir shorten the latency of tumors. In 2 *in vitro* cell transformation assays, used to provide preliminary assessment of potential oncogenicity in advance of these more definitive life-time bioassays in rodents, conflicting results were obtained. Acyclovir was positive at the highest dose used in one system and the resulting morphologically transformed cells formed tumors when inoculated into immunosuppressed, syngeneic, weanling mice. Acyclovir was negative in another transformation system considered less sensitive.

In acute studies, there was an increase, not statistically significant, in the incidence of chromosomal damage at maximum tolerated parenteral doses of 100 mg/kg acyclovir in rats but not Chinese hamsters; higher doses of 500 and 1000 mg/kg were clastogenic in Chinese hamsters. In addition, no activity was found after 5 days dosing in a dominant lethal study in mice. In 6 of 11 microbial and mammalian cell assays, no evidence of mutagenicity was observed. At 3 loci in a Chinese hamster ovary cell line, the results were inconclusive. In 2 mammalian cell assays (human lymphocytes and L5178Y mouse lymphoma cells *in vitro*), positive responses for mutagenicity and chromosomal damage occurred, but only at concentrations at least 400 times the acyclovir plasma levels achieved in man.

Acyclovir has not been shown to impair fertility or reproduction in mice (450 mg/kg/day, p.o.) or in rats (25 mg/kg/day, s.c.). At 50 mg/kg/day s.c. in the rat, there was a statistically significant increase in post-implantation loss, but no concomitant decrease in litter size. In female rabbits treated subcutaneously with acyclovir subsequent to mating, there was a statistically significant decrease in implantation efficiency but no concomitant decrease in litter size at a dose of 50 mg/kg/day. No effect upon implantation efficiency was observed when the same dose was administered intravenously. In a rat peri- and postnatal study at 50 mg/kg/day s.c., there was a statistically significant decrease in the group mean numbers of corpora lutea, total implantation sites and live fetuses in the F₁ generation. Although not statistically significant,

there was also a dose related decrease in group mean numbers of live fetuses and implantation sites at 12.5 mg/kg/day and 25 mg/kg/day, s.c. The intravenous administration of 100 mg/kg/day, a dose known to cause obstructive nephropathy in rabbits, caused a significant increase in fetal resorptions and a corresponding decrease in litter size. However, at a maximum tolerated intravenous dose of 50 mg/kg/day in rabbits, there were no drug-related reproductive effects.

Intraperitoneal doses of 320 or 80 mg/kg/day acyclovir given to rats for 1 and 6 months, respectively, caused testicular atrophy. Testicular atrophy was persistent through the 4-week post-dose recovery phase after 320 mg/kg/day; some evidence of recovery of sperm production was evident 30 days postdose. Intravenous doses of 100 and 200 mg/kg/day acyclovir given to dogs for 31 days caused aspermatogenesis. Testicles were normal in dogs given 50 mg/kg/day, i.v. for one month.

Pregnancy: Teratogenic Effects: Pregnancy Category C. Acyclovir was not teratogenic in the mouse (450 mg/kg/day, p.o.), rat (50 mg/kg/day, s.c.) or rabbit (50 mg/kg/day, a.c. and i.v.). There are no adequate and well-controlled studies in pregnant women. Acyclovir should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. Although acyclovir was not teratogenic in animal studies, the drug's potential for causing chromosome breaks at high concentration should be taken into consideration in making this determination.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Zovirax is administered to a nursing woman. In nursing mothers, consideration should be given to not using acyclovir treatment or discontinuing breastfeeding.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS — Short-Term Administration:

The most frequent adverse reactions reported during clinical trials were nausea and/or vomiting in 8 of 298 patient treatments (2.7%) and headache in 2 of 298 (0.6%). Less frequent adverse reactions, each of which occurred in 1 of 298 patient treatments (0.3%), included diarrhea, dizziness, anorexia, fatigue, edema, skin rash, leg pain, inguinal adenopathy, medication taste and sore throat.

Long-Term Administration: The most frequent adverse reactions reported in studies of daily therapy for 3 to 6 months were headache in 33 of 251 patients (13.1%), diarrhea in 22 of 251 (8.8%), nausea and/or vomiting in 20 of 251 (8.0%), vertigo in 9 of 251 (3.6%), and arthralgia in 9 of 251 (3.6%). Less frequent adverse reactions, each of which occurred in less than 3% of the 251 patients (see number of patients in parentheses), included skin rash (7), insomnia (4), fatigue (7), fever (4), palpitations (1), sore throat (2), superficial thrombophlebitis (1), muscle cramps (2), paronychia (1), menstrual abnormality (4), acne (3), lymphadenopathy (2), irritability (1), accelerated hair loss (1), and depression (1).

DOSAGE AND ADMINISTRATION: Treatment of initial genital herpes: One 200 mg capsule every 4 hours, while awake, for a total of 5 capsules daily for 10 days (total 50 capsules).

Chronic suppressive therapy for recurrent disease: One 200 mg capsule 3 times daily for up to 6 months. Some patients may require more drug, up to one 200 mg capsule 5 times daily for up to 6 months.

Intermittent Therapy: One 200 mg capsule every 4 hours, while awake, for a total of 5 capsules daily for 5 days (total 25 capsules). Therapy should be initiated at the earliest sign or symptom (prodrome) of recurrence.

Patients With Acute or Chronic Renal Impairment: One 200 mg capsule every 12 hours is recommended for patients with creatinine clearance ≤ 10 ml/min/1.73 m².

HOW SUPPLIED: Zovirax Capsules (blue, opaque) containing 200 mg acyclovir and printed with "Wellcome ZOVIRAX 200". Bottles of 100 (NDC-0081-0991-55) and unit dose pack of 100 (NDC-0081-0991-56).

Store at 15°-30°C (59°-86°F) and protect from light.

*In controlled studies, recurrences were totally prevented for 4 to 6 months in up to 75% of patients.



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Implications for Fee-for-Service Practices Affiliated with Independent Practice Associations

John J. Aluisse, Ph.D., Don Bradley, M.D.,
and Bill Zelman, C.P.A., Ph.D.

Prepaid health systems, especially health maintenance organizations (HMOs), have made a dramatic impact upon traditional patterns of medical practice. According to the 1985 HMO census report, over 20,000,000 people in the United States are enrolled in some form of HMO. The Independent Practice Association (IPA), which is the newest form of HMO, represents over 75% of prepaid plans and 55% of enrollees in HMOs. Utilization rates for group and staff HMOs are approximately 3.5 visits per enrollee per year, while in IPAs the average number of visits per enrollee per year is slightly over four.¹ The future growth in prepaid health plans is projected to be in the IPA plans because they require less organizational and financial investment and because they allow practicing physicians to incorporate prepaid patients into their traditional fee-for-service practices.

Beginning in 1982, nine HMOs, seven of which are IPAs, have enrolled over 300,000 people in North Carolina, representing nearly 5% of the state's population.² Since the largest number of enrollees in North Carolina have been in IPA plans, this type of HMO will have the most impact on practicing physicians in North Carolina.

The unique feature of IPA plans is that they allow practicing physicians to continue to provide services to fee-for-service patients, as well as those patients who are enrolled in the HMO. Physicians are compensated for medical care to the IPA plan subscribers on a capitation basis or on a fee-for-service basis. IPA plans typically require primary care physicians to act as health care managers for the patients enrolled in the IPA. This involves providing primary medical services and authorizing referrals and admissions. Primary physicians are also encouraged to carefully monitor patients' use of diagnostic tests and surgical procedures.

General Findings About HMOs

Most research on prepaid medical practice has concentrated on the staff and group types of HMO, which are typically operated as exclusive practices for prepaid patients. Wolinsky reviewed nine of the most often cited studies of HMO performance and identified the incentives and disincentives to operate an HMO.³ According to Wolinsky's review, HMOs lower the rate of hospitalization, reduce the average cost of medical care, offer a range of health benefits, minimize unnecessary surgery, and curb the over-utilization of tests and procedures inherent in the fee-for-service system. Quality of care in HMOs is generally comparable to fee-for-service practices, but patient satisfaction declines when continuity is poor and when higher utilization occurs. Evidence also seems to indicate that HMOs do not skim off healthy patients.

In a second major review, Ellsbury compiled an encyclopedia of information on the growth and current trends occurring in the HMO field.⁴ Characteristics common to successful HMOs are: adequate patient access; consumer grievance procedure; coordination of care, including consultation and referral services; restrictions on certain services, particularly hospital admissions and inpatient surgery; information management system; physician involvement in financial management and risk-sharing; protection against insolvency; negotiated prices for specialty and ancillary services; emphasis upon group practices; and effective medical and administrative leadership. In addition to these factors, Ellsbury concluded that if practices are to manage prepaid patients efficiently, they should consider including other health professionals such as nurse practitioners and physician assistants, and implementing administrative mechanisms within the practice to monitor utilization and coordinate the authorization process.

From the University of North Carolina, Department of Family Medicine, 269 H, Chapel Hill 27514.

Advantages and Disadvantages of IPAs

The IPA, like most HMOs, has five basic features: (1) a contractual relationship with primary care physicians to provide comprehensive health services; (2) a defined population enrolled for a set period; (3) voluntary participation by both providers and patients; (4) fixed payments to the primary physicians by the HMO; and (5) assumption of a portion of financial risk by the providers.⁵ More detailed discussion of the features and functions of IPA plans are available in several case studies and in a federally funded report.⁶⁻⁸

Despite the many positive features attributed to HMOs and publicized particularly to employers and the population at large, in certain instances the IPA plans have met with considerable negative reactions, particularly from physicians in fee-for-service practices. The two problems that physicians mention most often are that cost containment efforts result in lower quality of care, and that the doctor-patient relationships are compromised due to lack of choice of doctor leading to discontinuity of care and the potential for impersonal treatment.^{9,10} Table 1 outlines the major advantages and disadvantages that physicians need to consider when affiliating with IPA plans.

Some of the controversy surrounding IPAs may be attributed to the primary physician's role as case manager. The case manager role has been defined as "... designated health professional who serves as the patient's primary physician and refers the patient to specialist services, as needed, as a condition of third party payment for services."¹¹ This role is viewed as essential to the HMO concept because the success of prepaid plans is based on the extent to which the

primary physician, as case manager, limits unnecessary referrals to specialists.

Opposition to the primary care physician as case manager comes from specialists who fear that primary physicians will exert monopolistic control over the access to important medical services. Other problems associated with the case manager role are: (1) it has the potential to create adversarial relationships among patients and consultants and primary physicians over decisions about additional medical services; (2) it may generate ethical and professional conflicts when the physician's perception of what is medically indicated differs from the insurer's benefits; (3) administrative tasks by both physicians and their office personnel add time and expense which is not compensated in the prepayment contract; and (4) multiple IPAs in one practice may lead to inefficiency and confusion within the practice organization.¹²⁻¹⁴

Preliminary Research on IPAs in North Carolina

When family physicians in Charlotte, Greensboro, and the Durham-Chapel Hill area meet to discuss their initial experiences with IPAs, it becomes apparent that they have a variety of questions and concerns and a perception that many of the purported advantages have yet to be recognized. In these discussions, the doctors seem to be most worried about the following issues: the adequacy of capitation rate and physician compensation; the number of different types of services primary physicians must authorize; the amount of clerical and communications work required of primary physicians and office personnel; administrative support from the IPA organization to the physicians' offices; mechanisms for authorizations and negotiations with consultants and other preferred providers; disruptions in office efficiency; the perplexity of the case manager role; and the realities of the functioning of the prepaid system.

Even though our information is preliminary and may not represent the attitudes of all physicians affiliated with IPAs, we believe, based upon previous studies and our initial investigation, that physicians in North Carolina should be apprised of the following issues as they contemplate their association with prepaid plans.

Capitation rate. The capitation rate, which in the HMO is the primary physician's source of payment, appears to be inadequate to cover the cost of services customarily given to equivalent fee-for-service patients. This may be a function of the higher utilization during the initial period of the plan or the inadequacy of capitation rates for particular age/sex groups. Specific concerns were raised about the capitation rate for women aged 18-54, and about certain groups of health consumers who may be consistently high utilizers, such as hospital employees and elderly patients.

Special services in risk pool. Some of the services in the primary physician's risk pool may need to move into

Table 1
Advantages and Disadvantages of Affiliation with IPAs

Advantages	Disadvantages
Increase in patient enrollments	Potential adversarial relationships with patients/consultants/third parties
Predictable cash flow	Potential for higher utilization of office visits by prepaid patients
Increase in collections	Limitations on choice of referrals
Greater control over use of ancillary services and referrals	Financial risk if utilization is high or if adverse selection occurs
Potential for population-based research	Increased administrative tasks for physicians and office staff
Productivity analyses on utilization of primary and specialty care services	Greater demands upon the practice "cost-effectively"
Opportunity to participate in planning and implementing prepaid plans	Each physician's practice methods will be analyzed and compared
Opportunity to establish a multi-specialty referral network	
Greater rewards for practices with full-service labs and x-ray facilities	

the referral or institutional funds. These include psychiatric and other mental health services, chiropractic fees, prescription drugs, newborn hospital care, physical therapy, and medical care for major preexisting conditions. Many primary physicians indicated that they did not believe they should be at risk financially for services, such as these, that generally are not provided by primary physicians.

Administrative support by the IPA. A major area of concern for primary physicians is the insufficient administrative support provided by some IPAs. Common problems include a lack of guidelines for covered services, inaccessibility of IPA personnel to handle questions and complaints, the amount of paperwork required of the practice to record encounter and referral information about primary care and specialist utilization, costs incurred from referral and institutional funds, and other productivity information to evaluate the individual practice and overall success of the prepaid plan.

Preferred providers. Since the viability of prepaid plans, particularly IPAs, is determined by controlling the costs of specialty and ancillary services, primary care practitioners recognize the value of selecting a few consultants in each specialty with pre-arranged fees. A close relationship with specialists is essential, and primary physicians felt that consultants should be selected who were committed to working

within the guidelines of the prepaid plan. This arrangement could include radiology, laboratory services and counseling centers. Primary physicians felt that the IPA plans should make a special effort to communicate with specialists, to inform them about the requirements for referrals and to emphasize the primary physician's role as coordinator of the patient's medical care. Some IPAs do a much better job of dealing with the primary physician/consultant physician relationship than others.

Practice disruptions. The increase in patient enrollments and office visits within a relatively short period of time will disrupt office routines. Problems were reported in scheduling routine and acute visits for fee-for-service patients, in verifying membership of IPA patients, in dealing with eligibility requirements, and in responding to IPA patients' demands for preferential referrals. The influx of new patients will stress the practice system. Physicians and office personnel should be prepared to increase the number of available appointment times and establish protocols so that both fee-for-service and prepaid patients' requests can be satisfied. Additional staffing may also be needed to complete the registration procedures and to record financial and utilization data that the IPA plans require.

Marketing by the IPA. Physicians seemed in agreement that the prepaid plans are being marketed to employers and the general public as a comprehensive, low-cost method of health care, with easy access to specialists as long as the primary care physician gives permission. Many stipulations are either avoided or glossed over when presenting the plans to potential enrollees. Issues that primary physicians believe need to be clarified are the emphasis on the primary physician as health care manager, the need for appropriate justification before referrals and surgical procedures, the limitations on use of specialists, and the need to comply with established office practice routines. It appears that most plans are overzealous in their marketing efforts toward employers and future patients. In the future the plans must be more cognizant of the needs of their providers who ultimately must deliver the service that the plan promotes.

Case manager's role. The success of the IPA is predicated upon the primary physicians' ability not only to provide quality medical care but to coordinate and monitor in their respective practices all needed health services for the prepaid patients. Physician case management has been described as a range of roles including advocate, agent, care giver, diagnostician, risk manager, broker, educator, service evaluator, auditor, authorizer and resource allocator.¹⁵ Given that these roles require several hours per week of physician and staff time, the case manager function should be appropriately compensated. Suggestions for how this role should be rewarded varied from 10% of office staff salaries to an additional 10% to 15% added to the monthly capitation payment.

Table 2 presents a **Practice Readiness Checklist** that physicians could use to determine how prepared their practices are to affiliate with a prepaid health plan.

Table 2.
Practice Readiness Checklist

"Is your practice ready to affiliate with an IPA?"

Practice has a need to increase its patient population to include prepaid patients.

Financial payments from prepaid plan are considered appropriate for the volume and type of services that will be provided to patients enrolled.

Practice is willing to expand medical care and ancillary services to provide a wide range of clinical and diagnostic services.

One physician and the practice manager are prepared to devote several days/evenings per month working in various aspects of the IPA system.

All physicians in the practice are willing to have their practice styles and productivity analyzed, and compared to other practices.

Practice is willing to associate with other medical and surgical specialists (preferred providers) to control excessive utilization of medical care.

Primary care physicians are prepared to authorize (and deny) referrals and use of specialized care.

Practice is willing to establish an internal control system to evaluate quality of care, utilization of ancillary services, authorization of referrals and admissions, and the efficiencies of patient scheduling and other office routines.

Discussion

As physicians assess the pros and cons of prepaid health plans, particularly the IPA model, it behooves them to look closely at not only the individual plan but also their personal and organizational practice patterns. Integrating prepaid health plans into fee-for-service practices will undoubtedly change practice management and professional relations.

It is unlikely that prepaid health care will diminish in scope. All the signs are quite to the contrary. It is hoped that primary physicians and their consultant colleagues will find it worthwhile to incorporate the aims of prepaid plans which are to offer cost-effective, comprehensive health services to a defined group of patients on a prepaid basis.

Successful prepaid health plans will require physician leadership in all aspects of the system's design and implementation. Practitioners must be willing to work within the HMO organization to establish and refine utilization controls and peer review mechanisms and to promote the appropriate alternatives to hospitalizations and high-cost procedures. HMO organizations must provide physicians with professional and financial incentives for affiliating with prepaid health plans.

During the negotiation stage of either the initial contract or a renewal period, physicians would consider the issues listed in table 3 as they negotiate their affiliation agreement with the IPA. The following three sources of information regarding physicians contractual relationships with HMOs will also be of value during a negotiation process.

Physicians' Contracting Handbook

California Medical Association

731 Market Street, San Francisco, CA 94013

415/863-5522

Minnesota Medical Association

Suite 400, 2221 University Ave. S.E.

Minneapolis, MN 55414

612/378-1875

Compendium of Information on Considering a Contract
Socioeconomics Division

American Academy of Family Physicians

1740 W. 92 St., Kansas City, MO 64114

800/821-2512

A national study of HMO success factors concludes that a good relationship between an IPA and participating physicians will entail: reimbursement mechanisms and amounts that are perceived as fair; assistance in patient management such as advising on good office management practices and making available comparative data on utilization patterns; a balance between the need for adequate utilization controls and the avoidance of paperwork and procedural burdens; and a recognition of the physician's desire for clinical independence.¹⁶ ■

Table 3.

Factors to Consider During Contractual Negotiations with an IPA

- 1 Marketing information presented to employers and enrollees about primary care providers, consultants, and covered and non-covered services.
- 2 Limitations on hospitalizations, referrals, and ancillary services.
- 3 Obligations of the providers to enrolled patients and the plan itself.
- 4 Requirements for prior authorization by the primary physician.
- 5 Definition of services included in capitation, referral and institutional funds.
- 6 Renegotiation procedures for capitation rates and assignment of patients.
- 7 Disbursement of payment from the capitation-referral and institutional funds.
- 8 Availability and usefulness of management information reports.
- 9 Support services and grievance procedures of the plan.
- 10 Physician representation in the IPA's administrative system.
- 11 Medical-legal and malpractice considerations affecting the affiliation.
- 12 Negotiated fees and contracted services with preferred providers.
- 13 Utilization review and cost containment policies.
- 14 Stop-loss guidelines and other methods for exceptional circumstances.
- 15 Termination provisions and obligations of both parties upon termination.

Important Questions

How is insurance premium distributed? How is allowance for hospitalization and referral funds calculated? What is preadmission certification system?

What is the risk sharing/hold back provision? How are out-of-area services covered? How are primary physicians' services marketed? How are consultant costs controlled? What is stop-loss for physician and hospital costs?

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***See Warnings and Precautions.**

Please see brief summary of prescribing information on the next page





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Brief Summary

Professional Use Information

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CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

- Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1,243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
- Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
- Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
- Acute Hepatic Injury.** In rare instances, significant elevations in enzymes such as alkaline phosphatase, CPK, LDH, SGOT, SGPT, and other symptoms consistent with acute hepatic injury have been noted. These reactions have been reversible upon discontinuation of drug therapy. The relationship to CARDIZEM is uncertain in most cases, but probable in some. (See PRECAUTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic

function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS.)

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in *in vitro* bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy, Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. Diltiazem is excreted in human milk. One report suggests that concentrations in breast milk may approximate serum levels. If use of CARDIZEM is deemed essential, an alternative method of infant feeding should be instituted.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably asso-

ciated with the pharmacology of calcium influx inhibition in many cases, the relationship to CARDIZEM has not been established. The most common occurrences as well as their frequency of presentation are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%). In addition, the following events were reported infrequently (less than 1%):

Cardiovascular	Angina, arrhythmia, AV block (first degree), AV block (second or third degree) — see conduction warning, bradycardia, congestive heart failure, flushing, hypotension, palpitations, syncope.
Nervous System	Amnesia, gait abnormality, hallucinations, insomnia, nervousness, paresthesia, personality change, somnolence, tinnitus, tremor.
Gastrointestinal	Anorexia, constipation, diarrhea, dysgeusia, dyspepsia, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH (see hepatic warnings), vomiting, weight increase.
Dermatologic	Petechiae, pruritus, photosensitivity, urticaria.
Other	Amblyopia, dyspnea, epistaxis, eye irritation, hyperglycemia, nasal congestion, nocturia, osteoarthralgia, pain, polyuria, sexual difficulties.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: alopecia, gingival hyperplasia, erythema multiforme, and leukopenia. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

See complete Professional Use Information before prescribing.

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Buspirone

Just Another Antianxiety Agent?

Timothy E. Poe, Pharm.D.

Buspirone (Buspar[®]), the newest anxiolytic marketed in the United States, offers several possible advantages over currently available drugs such as benzodiazepines. Buspirone alleviates anxiety as do the benzodiazepines, but causes less sedation and functional impairment. It also lacks the abuse potential and tendency to cause physical dependence.¹ However, buspirone does not have the anticonvulsant and muscle relaxant effects the benzodiazepines have.

Buspirone is both chemically and pharmacologically distinct from the benzodiazepines and other antianxiety agents. Although the mechanism of action of buspirone is not precisely known, it appears to be different from that of the benzodiazepines.

Buspirone has been shown to be clinically effective for the treatment of anxiety. In general the drug's potency has been shown to equal that of diazepam on a mg-to-mg basis. Most studies have used four weeks as the duration of treatment and compared buspirone to diazepam, lorazepam, alprazolam, and clorazepate.²⁻⁵

The most frequently reported side effects for buspirone are dizziness, nausea, headache, nervousness, lightheadedness, and excitability.⁶ The more common events that have caused discontinuation of treatment are: central nervous system disturbances (3.4%), primarily in the form of dizziness, insomnia, nervousness, drowsiness, and lightheadedness; gastrointestinal disturbances (1.2%), primarily nausea; and miscellaneous disturbances (1.1%), primarily headache and fatigue. Few if any drug interactions have been documented with buspirone, nor has it been shown to interact with alcohol or other central nervous system depressants.⁷

Several studies have evaluated the effects of buspirone on psychomotor performance. In driving skills tests, buspirone has been shown to have no effect or even to improve performance compared to diazepam or alcohol.²

Buspirone appears to be a good choice for initiating therapy in anxious patients, particularly those patients prone to the misuse of medications. In general, patients with prior benzodiazepine use take longer to respond or do not respond as well with buspirone. It is also important to realize that buspirone will not block the benzodiazepine withdrawal syndrome. Buspirone, however, may be abruptly discontinued, as it does not appear to have a withdrawal syndrome. While buspirone is an effective anxiolytic, it is not a good p.r.n. medication. The manufacturer recommends that treatment be continued for at least three to four weeks for full therapeutic benefit.⁸

Initial dosage should be 5 mg three times daily. The dosage may be adjusted every two to three days as needed, up to 60 mg/day. For most patients, 20-30 mg/day in divided doses will be optimal.⁸ Cost of Buspar[®] (AWP) is slightly greater than brand-name benzodiazepines such as Valium[®]. Generics, where available, will be less expensive. However, it is difficult to compare strictly on cost since buspirone may have advantages over currently utilized benzodiazepines. ■

Acknowledgment

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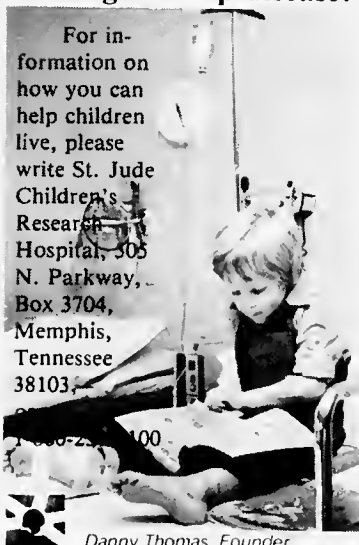
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From the Department of Family and Community Medicine, and Pharmacy Education of Northwest Area Health Education Center, Bowman Gray School of Medicine of Wake Forest University, 300 S. Hawthorne Rd., Winston-Salem 27103; and School of Pharmacy, University of North Carolina, Chapel Hill 27514.

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Contraindications: Known hypersensitivity to the drug.

Warnings: Warn patients that mental and/or physical abilities required for tasks such as driving or operating machinery may be impaired, as may be mental alertness in children, and that concomitant use with alcohol or CNS depressants may have an additive effect. Though physical and psychological dependence have rarely been reported on recommended doses, use caution in administering to addiction-prone individuals or those who might increase dosage. Withdrawal symptoms (including convulsions) reported after abrupt cessation of extended use of excessive doses are similar to those seen with barbiturates. Milder symptoms reported infrequently when continuous therapy is abruptly ended. Avoid abrupt discontinuation; gradually taper dosage.

Usage in Pregnancy: Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Precautions: In the elderly and debilitated, and in children over six, limit to smallest effective dosage (initially 10 mg or less per day) to preclude ataxia or oversedation, increasing gradually as needed and tolerated. Not recommended in children under six. Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider individual pharmacologic effects, particularly in use of potentiating drugs such as MAO inhibitors and phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions (e.g., excitement, stimulation and acute rage) have been reported in psychiatric patients and hyperactive aggressive children. Employ usual precautions in treatment of anxiety states with evidence of impending depression; suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation have been reported very rarely in patients receiving the drug and oral anticoagulants, causal relationship has not been established clinically. Due to isolated reports of exacerbation, use with caution in patients with porphyria.

Adverse Reactions: Drowsiness, ataxia and confusion may occur, especially in the elderly and debilitated. These are reversible in most instances by proper dosage adjustment, but are also occasionally observed at the lower dosage ranges. In a few instances syncope has been reported. Also encountered are isolated instances of skin eruptions, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased libido—all infrequent and generally controlled with dosage reduction, changes in EEG patterns (low-voltage fast activity) may appear during and after treatment; blood dyscrasias (including agranulocytosis), jaundice and hepatic dysfunction have been reported occasionally, making periodic blood counts and liver function tests advisable during protracted therapy.

Usual Daily Dosage: Individualize for maximum beneficial effects. **Oral—Adults:** Mild and moderate anxiety disorders and symptoms, 5 or 10 mg t.i.d. or q.i.d.; severe states, 20 or 25 mg t.i.d. or q.i.d. **Geriatric patients:** 5 mg b.i.d. to q.i.d. (See Precautions).

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Letters to the Editor

Dr. Dykers's reply to Drs. MacCormack and Meriwether

To the Editor:

Thank you for publishing my advertisement about the AIDCARD and for publishing Dr. MacCormack's and Meriwether's concerns (NCMJ 48:226-7, 236). I certainly share many of those concerns, to the point of having changed the name from SAFECARD to AIDCARD. We must be careful to diminish risks realistically and not with false expectations. Whereas it is vital to reduce hysteria about AIDS as transmissible in the classroom and a work place, anyone who is not frightened of AIDS as a sexually transmitted and blood borne disease is foolish. Our next immediate struggle is to recognize AIDS as a heterosexual disease.

For this reason, I think it is very important to bring people into the medical care system for proper interpretation of laboratory results and for counselling as to how to behave on that basis. We have invited Dr. Ron Levine to the Thursday Morning Intellectual Society on the 7th of May 1987 to give us his views on these matters.

However, overstatements, such as saying that treatment services for Hepatitis B are available free of charge at all local health departments, are misleading. Confidentiality is precarious at best and anonymity is automatically lost when counselling begins. That trade-off is inescapable. By protecting anonymity at the stage of test results, we hope to be able to encourage people to voluntarily give up their anonymity and enter into a confidential counselling relationship.

Drs. MacCormack and Meriwether may wish in the future to refrain from telling us what "absolutely must accompany all screening for communicable diseases." We have not, in recent memory, faced a communicable disease with such a high fatality rate and no cure and such a long asymptomatic infectious carrier state. Plague, typhoid, TB, polio, and syphilis are going to appear as minor annoyances in comparison. The Division of Health Services will be overwhelmed and they will come to appreciate every private effort.

One often tends to glibly throw around such terms as safe sex.¹ Safe is a relative word, certainly as regards AIDS. The most important consideration is that of motivation. A person most highly motivated to practice safe sex is that person who is negative for HTLV-III antibodies and wants to stay

that way. Our health department has already recognized the difficulties of some persons who are antibody positive and who do not possess the altruistic motivations to refrain from continuing to spread the virus. It is a grave threat to the public health to ignore the tremendous value of creating a body of tested negatives who are highly motivated to stay negative.

An ounce of prevention is worth a pound of cure, and when you have no cure, that dictum reaches astronomical proportions. Whereas it is most appropriate for public tax monies to be directed toward the highest risk groups and high yields, it is equally appropriate for private monies to seek peace of mind. One of the values of our AIDCARD system is that it is easy to utilize in most physicians' offices. All that is required is a phlebotomy, a centrifuge, and a mailbox.

Much of the basis for the objections to the AIDCARD voiced by Drs. MacCormack and Meriwether became obsolete by the time the letter was written. The most dangerous person in our society today is the heterosexual who was previously thought of as being in a low risk group and who has the HIV virus and does not know it and continues to spread the same.¹ The inclusion of the Chlamydia antibody test is solely done to pull people into the system for further evaluation. At the recent International Conference on AIDS in children, adolescents, and heterosexual adults in Atlanta, Georgia, Dr. Nathan Clumeck of St. Pierre Hospital in Brussels, Belgium said, "the occurrence of a previous or concurrent sexually transmitted disease is crucial." He suspects that females may well be at much greater risk for the virus than males and that inflammation of the genitourinary tract is a major facilitator of virus transfer.

We have so much yet to learn. I'm sure I'll change my mind about many things about this disease as time passes and our knowledge increases. I expect we all will have to do that. But for now, I fully expect the AIDCARD profile to become a standard of care for anyone who has a sexually transmitted disease and I fully expect it to soon be well accepted as a valuable tool in promoting safe sex.

John R. Dykers, Jr., M.D.

P.O. Box 565
Siler City 27344

¹ Goedert JJ. What is safe sex? *New Engl J Med* 1987;316:1339-42.

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*** WARNING**

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K⁺ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K⁺ intake. Associated widened QRS complex or arrhythmia requires prompt additional therapy. Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: The bioavailability of the hydrochlorothiazide component of 'Dyazide' is about 50% of the bioavailability of the single entity. Theoretically, a patient transferred from the single entities of triamterene and hydrochlorothiazide may show an increase in blood pressure or fluid retention. Similarly, it is also possible that the lesser hydrochlorothiazide bioavailability could lead to increased serum potassium levels. However, extensive clinical experience with 'Dyazide' suggests that these conditions have not been commonly observed in clinical practice. Angiotensin-converting enzyme (ACE) inhibitors can elevate serum potassium, use with caution with 'Dyazide'. Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide, dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function. Thiazides may add to or potentiate the action of other antihypertensive drugs. Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth, anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions, nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

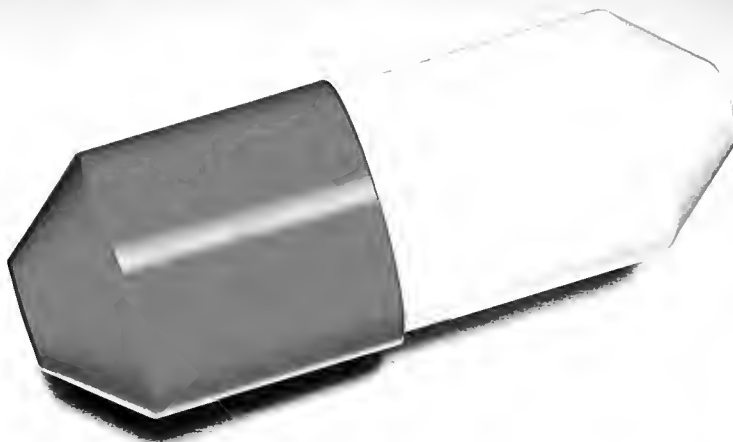
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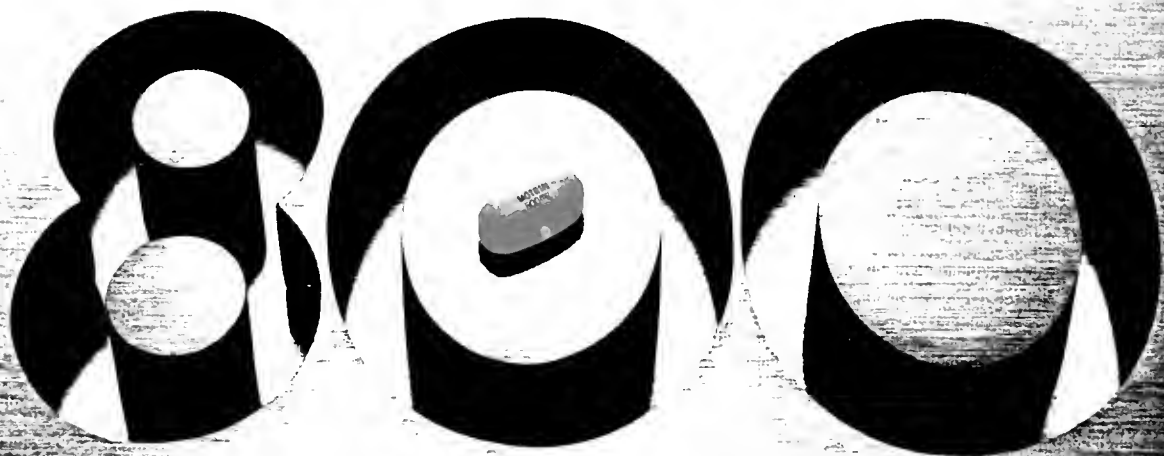
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IN STATE

June 11-13

34th Annual Mountaintop Medical Assembly

Place: Waynesville

Info: George W. Brown, M.D., Mountaintop Medical Assembly, Waynesville 28786. 704/456-6021

June 15-17

Surgery for Coronary Artery Disease

Place: Durham

Fee: \$460 ACC members; \$525 others

Credit: 17 hours Category I ACCME

Info: Registration Secretary, Extramural Programs Dept, American College of Cardiology, 9111 Old Georgetown Rd., Bethesda, MD 20814. 800/253-4636; in MD or AK 301/897-5400

July 3-5

NCMS 17th Annual Sports Medicine Symposium

Place: Wrightsville Beach

Info: W. Alan Skipper, 919/833-3836 or 800/722-1350

July 13-15

U.S. Olympic Festival Sports Medicine Conference: Part II, Athletic Injury Prevention and Treatment

Place: Durham

Credit: pending

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

July 13-17

29th Annual Postgraduate Course/Morehead Symposium

Place: Durham

Credit: 26 hours Category I AMA; AAFP 24.75 prescribed

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

July 27-31

10th Annual Radiology Postgraduate Course

Place: Atlantic Beach

Credit: 20 hours Category I AMA

Info: Cynthia C. Easterling, M.Ed., Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 or 684-6485; outside NC 800/222-9984

August 14-16

Family Physicians Weekend

Place: Wrightsville Beach, NC

Credit: 12 hours AAFP

Info: Paula Baker, Meeting Coordinator, North Carolina Academy of Family Physicians, P.O. Box 18469, Raleigh 27619. 919/781-6467

August 22-23

Urology — State of the Art

Place: Winston-Salem

Fee: \$200

Info: CME Coordinator, Dept. of CME, AMA, 535 N. Dearborn St., Chicago IL, 60610. 312/645-4952

NCMJ will no longer publish an out-of-state Continuing Medical Education list.

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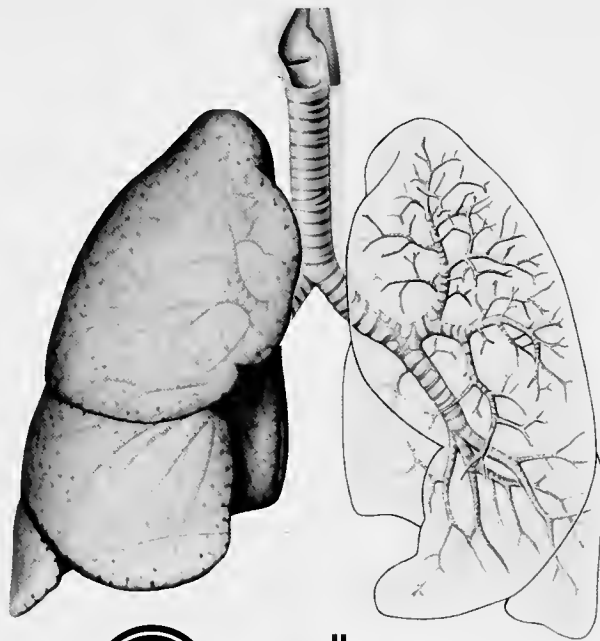
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Indications: Lower respiratory infections, including pneumonia, caused by susceptible strains of *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Streptococcus pyogenes* (group A β -hemolytic streptococci).

Contraindication:
Known allergy to cephalosporins.

Warnings:
CECLOR SHOULD BE ADMINISTERED CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. PENICILLINS AND CEPHALOSPORINS SHOW PARTIAL CROSS-ALLERGENICITY. POSSIBLE REACTIONS INCLUDE ANAPHYLAXIS.

Administer cautiously to allergic patients. Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis.

Precautions:

- Discontinue Ceclor in the event of allergic reactions to it.
- Prolonged use may result in overgrowth of nonsusceptible organisms.
- Positive direct Coombs' tests have been reported during treatment with cephalosporins.
- Ceclor should be administered with caution in the presence of markedly impaired renal function. Although dosage adjustments in moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made.
- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
- Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients.

Adverse Reactions: (percentage of patients)
Therapy-related adverse reactions are uncommon. Those reported include:

- Gastrointestinal (mostly diarrhea): 2.5%.
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment.
- Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, and serum-sickness-like reactions that have included erythema multiforme [rarely, Stevens-Johnson syndrome] or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever): 1.5%, usually subside within a few days after cessation of therapy. Serum-sickness-like reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.
- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.
- As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.
- Rarely, reversible hyperactivity, nervousness,

insomnia, confusion, hypertonia, dizziness, and somnolence have been reported.

- Other: eosinophilia, 2%; genital pruritus or vaginitis, less than 1%; and, rarely, thrombocytopenia.

Abnormalities in laboratory results of uncertain etiology

- Slight elevations in hepatic enzymes
- Transient fluctuations in leukocyte count (especially in infants and children)
- Abnormal urinalysis, elevations in BUN or serum creatinine
- Positive direct Coombs' test.
- False-positive tests for urinary glucose with Benedict's or Fehling's solution and Clinitest[®] tablets but not with Tes-Tape[®] (glucose enzymatic test strip, Lilly).

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Index to Advertisers

AIDCARD	343	Marion Laboratories, Inc.	340a-b
B & B X-Ray, Inc.	352	Medical Mutual Insurance Company of N.C.	346
Burroughs Wellcome Co.	315, 332a-b, 333	Medical Protective Company	301
Campbell Laboratories, Inc.	338	National Staffing Services Corp.	297
Capital Placements	343	NCNB	309
Charter Northridge Hospital	310	Roche Laboratories ...	305-306, 310-311, 339, 344-345, Cover 3-4
Communications Properties	298	Sharon Luggage & Gifts	342
Crumpton Company	Cover 2	Smith Kline & French	348a
Eli Lilly & Company	351	The Upjohn Company	348b
Focus: Healthcare	343	U.S. Army and Army Reserve	340
Glaxo/Roche	316a-d	U.S. Army Reserve	300
Hinrichs Financial Group	302	Winchester Surgical Supply Co.	314
Management Systems, Inc.	316		

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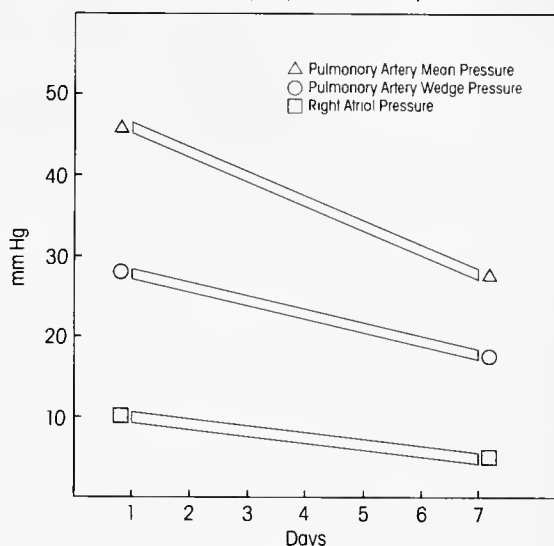
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References: 1. Olesen KH, *et al*. *Postgrad Med J* 51(Suppl 6): 54-63, 1975. 2. Handler B, Dhingra RC, Rosen KM. *J Clin Pharmacol* 21: 706-711, Nov-Dec 1981. 3. Brater DC, *et al*. *Clin Pharmacol Ther* 34: 207-213, Aug 1983. 4. Brater DC, Fox WR, Chennavasin P. *J Clin Pharmacol* 21: 599-603, Nov-Dec 1981. 5. Davies DL, *et al*. *Clin Pharmacol Ther* 15: 141-155, Feb 1974.

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WARNING: Bumex (bumetanide/Roche) is a potent diuretic which, if given in excessive amounts, can lead to a profound diuresis with water and electrolyte depletion. Therefore, careful medical supervision is required, and dose and dosage schedule have to be adjusted to the individual patient's needs. (See under **DOSAGE AND ADMINISTRATION** in complete product information.)

INDICATIONS AND USAGE: Edema associated with congestive heart failure, hepatic and renal disease, including the nephrotic syndrome.

Almost equal diuretic response occurs after oral and parenteral administration of Bumex. If impaired gastrointestinal absorption is suspected or oral administration is not practical, Bumex should be given by the intramuscular or intravenous route.

Successful treatment with Bumex following instances of allergic reactions to furosemide suggests a lack of cross-sensitivity.

CONTRAINDICATIONS: Anuria. Hypersensitivity and in patients in hepatic coma or in states of severe electrolyte depletion. Although Bumex can be used to induce diuresis in renal insufficiency, any marked increase in blood urea nitrogen or creatinine, or the development of oliguria during therapy of patients with progressive renal disease, is an indication for discontinuation of treatment.

WARNINGS: Dose should be adjusted to patient's needs. Excessive doses or too frequent administration can lead to profound water loss, electrolyte depletion, dehydration, reduction in blood volume and circulatory collapse with the possibility of vascular thrombosis and embolism, particularly in elderly patients.

Prevention of hypokalemia requires particular attention in patients receiving digitalis and diuretics for congestive heart failure, hepatic cirrhosis and ascites, states of aldosterone excess with normal renal function, potassium-losing nephropathy, certain diarrheal states, or other states where hypokalemia is thought to represent particular added risks to the patients.

In patients with hepatic cirrhosis and ascites, sudden alterations of electrolyte balance may precipitate hepatic encephalopathy and coma. Treatment in such patients is best initiated in the hospital with small doses and careful monitoring of the patient's clinical status and electrolyte balance. Supplemental potassium and/or spironolactone may prevent hypokalemia and metabolic alkalosis in these patients.

In cats, dogs and guinea pigs, Bumex has been shown to produce ototoxicity. Since Bumex is about 40 to 60 times as potent as furosemide, it is anticipated that blood levels necessary to produce ototoxicity will rarely be achieved. The potential for ototoxicity increases with intravenous therapy, especially at high doses.

Patients allergic to sulfonamides may show hypersensitivity to Bumex.

PRECAUTIONS: Measure serum potassium periodically and add potassium supplements or potassium-sparing diuretics, if necessary. Periodic determinations of other electrolytes are advised in patients treated with high doses or for prolonged periods, particularly in those on low salt diets. Hypernatremia may occur. Reversible elevations of the BUN and creatinine may occur, especially with dehydration and in patients with renal insufficiency. Bumex may increase urinary calcium excretion.

Possibility of effect on glucose metabolism exists. Periodic determinations of blood sugar should be done, particularly in patients with diabetes or suspected latent diabetes.

Patients should be observed regularly for possible occurrence of blood dyscrasias, liver damage or idiosyncratic reactions.

Especially in presence of impaired renal function, use of parenterally administered Bumex should be avoided in patients to whom aminoglycoside antibiotics are also being given, except in life-threatening conditions.

Drugs with nephrotoxic potential and bumetanide should not be administered simultaneously. Since lithium reduces renal clearance and adds a high risk of lithium toxicity, it should not be given with diuretics.

Probenecid should not be administered concurrently with Bumex.

Concurrent therapy with indomethacin not recommended.

Bumex may potentiate the effects of antihypertensive drugs, necessitating reduction in dosage.

Interaction studies in humans have shown no effect on digoxin blood levels.

Interaction studies in humans have shown Bumex to have no effect on warfarin metabolism or on plasma prothrombin activity.

Pregnancy: Bumex should be given to a pregnant woman only if the potential benefit justifies the potential risk to the fetus.

Bumetanide may be excreted in breast milk.

Pediatric Use: Safety and effectiveness below age 18 not established.

ADVERSE REACTIONS: Muscle cramps, dizziness, hypotension, headache and nausea, and

encephalopathy (in patients with preexisting liver disease).

Less frequent clinical adverse reactions are weakness, impaired hearing, rash, pruritus, hives,

electrocardiogram changes, abdominal pain, arthritic pain, musculoskeletal pain and vomiting.

Other clinical adverse reactions are vertigo, chest pain, ear discomfort, fatigue, dehydration,

sweating, hyperventilation, dry mouth, upset stomach, renal failure, asterixis, itching, nipple tenderness, diarrhea, premature ejaculation and difficulty maintaining an erection.

Laboratory abnormalities reported are hypernatremia, azotemia, hyperglycemia, increased serum

creatinine, hypochloremia, hypokalemia, hyponatremia, and variations in CO₂ content,

bicarbonate, phosphorus and calcium. Although manifestations of the pharmacologic action of

Bumex, these conditions may become more pronounced by intensive therapy.

Ouresis induced by Bumex may also rarely be accompanied by changes in LQH, total serum

bilirubin, serum proteins, SGOT, SGPT, alkaline phosphatase, cholesterol, creatinine clearance,

deviations in hemoglobin, prothrombin time, hematocrit, platelet counts and differential counts

in urine glucose and urinary protein have also been seen.

DOSAGE AND ADMINISTRATION:

Oral Administration: The usual total daily dosage is 0.5 to 2.0 mg and in most patients is given as a single dose.

Parenteral Administration: Administer to patients (IV or IM) with GI absorption problem or who cannot take oral. The usual initial dose is 0.5 to 1 mg given over 1 to 2 minutes. If insufficient response, a second or third dose may be given at 2 to 3 hour intervals up to a maximum of 10 mg a day.

HOW SUPPLIED: Tablets, 0.5 mg (light green), 1 mg (yellow) and 2 mg (peach), bottles of 100

and 500, Prescription Paks of 30, Tel-E-Dose[®] cartons of 100. Imprint on tablets: 0.5 mg—

ROCHE BUMEX 0.5, 1 mg—ROCHE BUMEX 1, 2 mg—ROCHE BUMEX 2.

Ampuls: 2 ml, 0.25 mg/ml, boxes of ten.

Vials: 2 ml, 4 ml and 10 ml, 0.25 mg/ml, boxes of ten.



ROCHE LABORATORIES
Division of Hoffmann-La Roche Inc.
Nutley, New Jersey 07110

ROCHE

OVERLOAD

Reduce fluid volume and improve hemodynamics in CHF

Edema due to congestive heart failure often demands highly effective diuresis to reduce the fluid load on the failing heart. Bumex® (bumetanide/Roche) is the next generation in loop diuretic therapy for three powerful reasons. It moves out an unsurpassed volume of fluid and sodium, resulting in significant reductions in edema and right atrial and pulmonary artery wedge pressures.^{1,2} It's almost completely absorbed through the GI tract, so it's easy to

titrate.³ And Bumex completes high-volume diuresis fast—within four hours at usual doses.^{4,5} Your patients spend less time in diuresis, more time in normal activities.

Bumex has a good safety profile; however, as with all loop diuretics, Bumex, if given in excessive amounts, can lead to profound diuresis with water and electrolyte depletion, including hypokalemia. Serum electrolytes should be monitored periodically, especially in patients on low salt diets or those treated for prolonged periods or on high doses.



Bumex®
bumetanide/Roche

0.5-mg, 1-mg and 2-mg scored tablets, 2-ml ampuls and 2-ml, 4-ml and 10-ml vials (0.25 mg/ml)

**First line
loop diuretic therapy**

Please see references and summary of product information on preceding page.
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